FINAL

STANDARD OPERATING PROCEDURES:

INVESTIGATING AND MANAGING LEAD RISKS AT NAVY INSTALLATIONS

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June 2005

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EXECUTIVE SUMMARY

This document presents a standard operating procedure (SOP) for evaluating and managing lead (Pb) related risks at Navy Installations. This SOP is intended to provide guidance to project teams who need to investigate the potential for lead exposures and associated elevated human health risks at the following types of sites:

- Family housing and residential habitation (non-dwelling property used by children, i.e. playgrounds, daycare, schools etc.) with Lead Based Paint (LBP) being considered for management transfer from the Navy to a Public/Private Venture (PPV);
- Isolated family housing (not part of a Defense Environmental Restoration Program (DERP) site) with LBP at a Navy Installation not located on or adjacent to a Defense Environmental Restoration Program (DERP) sites being considered for transfer of Navy Real Property; and
- Defense Environmental Restoration Program (DERP) sites potentially contaminated with Pb (but not LBP) that are undergoing CERCLA or RCRA investigations;

The major goals of this SOP are to:

- Provide an overview of applicable Federal Regulations, Laws, Policy, Cleanup Standards, and Risk Assessment Guidance for sites containing LBP and uncontrolled releases of other lead sources;
- Provide details on the agreed upon framework for transfer of LBP-containing housing units and also for transferring management of LBP properties to the private sectors;
- Provide a framework for investigating human health risks at non-LBP sites and the technical tools necessary for making cost-effective and health protective risk

management decisions;

This SOP is organized into the following chapters:

- ***Chapter 1: Introduction***
- ***Chapter 2: Investigating Navy Residential Housing With LBP***
- ***Chapter 3: Investigating CERLA and RCRA Sites with Pb Risk Assessments Models***

Chapter 1 This chapter presents a road map for project teams investigating various lead sites. A flow chart illustrates the general requirements for different sites that may be contaminated with different forms of Pb. Background information on the toxicity of lead and risks associated with excess exposure for both children and adults is also provided. This information is presented to provide a framework for risk management decisions where the results of Pb risk assessments, the results of which will be the predicted Pb blood (PbB) levels) are compared to health-based acceptable safe levels. The USEPA policy and risk management framework for Pb risk assessments are presented together with an overview of pertinent federal standards.

Chapter 2 provides information and guidance used to investigate LBP residential habitation (which include residential housing, playgrounds, day care facility, etc.) sites. This guidance was developed by the Department of Defense (DOD) and Department of the Navy (DON) and can be used, with few exceptions, where the purpose of the investigation is to either transfer management or the residential real property from the Navy to a public or private venture (PPV) under the Base Realignment and Closure (BRAC) Program. These guidelines are based on Title X/Toxic Substances Control Act (TSCA) requirements and are supported by a memorandum co-signed by USEPA and DOD. The purpose of the guidance was to streamline an approach in a cost-effective manner to meet (or exceed) federal requirements, which require a hazard assessment of Pb exposure. All steps in the investigation of possible health hazards associated with LBP at a particular site are prescriptive and well-defined enabling the Navy to arrive at comparable and consistent results at all similar LBP sites.

Chapter 3 provides information for Navy project teams who are conducting site investigations under either CERCLA or RCRA requirements where an uncontrolled release of Pb (but *not* in the form of LBP) was thought to occur. At these sites, a human health risk assessment is required to determine the potential for exposures to exceed safe PbB levels. Unlike LBP sites that are

governed by specific federal regulations, a human health Pb risk assessments is a scientific study of the site-specific exposure and toxicity of Pb. Sufficient information is provided in this chapter to tailor the Pb risk assessment to site-specific characteristics and project team requirements. Project teams should carefully weigh the advantages and disadvantages of the several approaches described in this chapter because different study designs vary in terms of complexity and level of effort. These criteria should be weighed when considering the overall cost of remediation. The following four lead risk assessment models used to estimate PbB levels and determine potential health risks are presented:

- The USEPA *Integrated Exposure Uptake Biokinetic* (*IEUBK*) Model;
- The USEPA *Adult Lead* (*AL*) Model;
- California Department of Toxic Substance Control (DTSC) California LeadSpread (Ca*LS)* Model; and
- USEPA Region 8, *Integrated Stochastic Exposure* (*ISE*) Model.

Criteria for choosing the correct model should be based on a conceptual site model (CSM) developed for a particular site. The model(s) selected by the project team should be part of a tiered framework, which guides the risk assessor in advancing from a screening type of risk assessment (based primarily on *non*-site specific default assumptions) to a more sophisticated site-specific risk assessment where additional site-specific data and information is gathered.

1.0 INTRODUCTION

1.1 Lead Investigations at Navy Installations

Navy installations requiring investigations into potential Pb exposures and elevated human health risks fall into one of two broad categories based on the physical or chemical state of Pb: (1) sites wit residential housing containing LBP (LBP) or, (2) sites thought to have past uncontrolled releases of Pb (non-LBP sources). The reason for the distinction is that a prescriptive framework of Federal policies, laws, and regulations has been developed specifically for LBP sites whereas no uniform federal standards exist for non-LBP. Figure 1 presents a flow chart that describes the type of investigations that are required for both types of sites and the policy and guidance that has been developed for each. This figure also provides the section in this SOP where details about the design of the lead study can be found.

Federal rules and regulations have been developed for LBP housing with the express purpose of preventing or mitigating lead exposure to young children who are at greatest risk. These Federal rules form the basis of several Navy policy memorandum and field guides that have been developed to expedite investigation, remediation, and ultimately transfer of the real properties or their management to other public or private sectors. This Navy guidance meets or exceeds all Federal regulations and provides a streamlined process.

For non-LBP sites investigated under CERCLA or RCRA project teams, a human health risk assessment is usually required to show that current or future exposures do not pose unacceptable risk particularly to children. Although lead risk assessments can be complex, this SOP presents a tiered approach that can be used to minimize the level of effort required at several important stages of investigation. This approach involves starting with a cost-effective screening step and only increasing the complexity of the investigation as warranted by site-specific requirements or remediation costs. Although there are several lead models of varying complexity and data needs that project teams can use in Pb risk assessments all have been developed to provide a common result, namely, predict the Pb-blood levels in the most sensitive population at risk which are either the developing fetus or young children. However, each lead model is slightly different with varying data needs. This SOP presents the advantages and disadvantages of each model so the appropriate Pb model can be selected based on specific site characteristics and sampling and analysis data requirements to enable the project team to: (1) effectively communicate the results

of the risk assessment to the public; (2) ensure public health will be protected, and (3) implement cost-effective informed risk management decisions.

Exhibit 1 presents a flow chart for diverse investigations the Navy is conducting at Pb sites that have are potentially contaminated with different physical and chemical forms of Pb. Numerous, and sometimes conflicting policies and guidance, have been developed over the last decade for investigating these sites. DOD and DON have attempted to develop clear guidance for specific sites and have reached consensus on a uniform approach. Although there may be a few exceptions, the flow chart provides and overview of necessary requirements for the vast majority of Pb sites along with sections of this SOP that provide detailed guidance. For those few sites that have several competing interests that pose unique challenges and that may not be explicitly covered in this SOP, experts at the Navy Environmental Health Center (NEHC) are available to provide additional technical advise that can be tailored to site-specific requirements and needs.

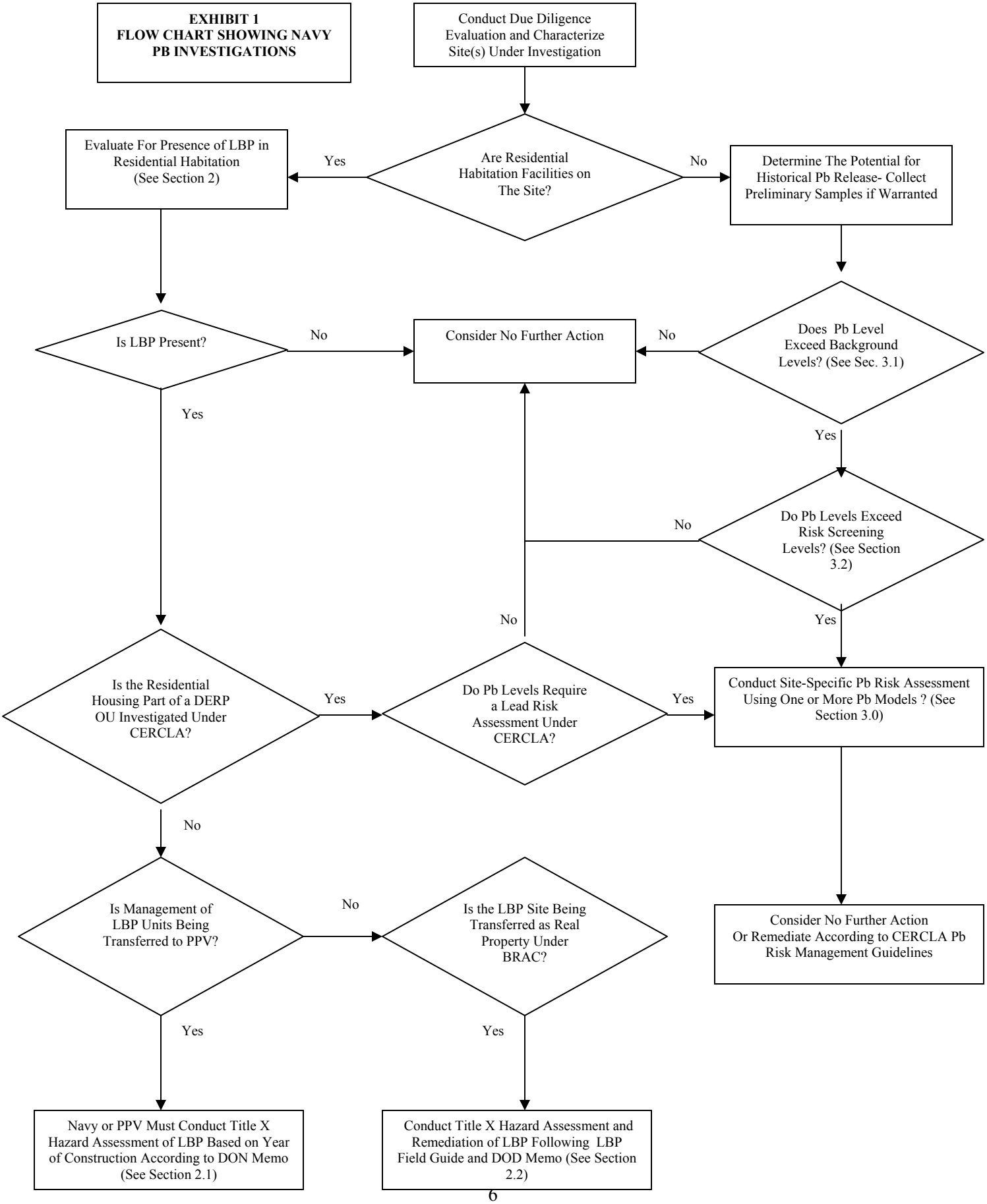


EXHIBIT 1
FLOW CHART SHOWING NAVY
PB INVESTIGATIONS
Conduct Due Diligence Evaluation and Characterize Site(s) Under Investigation
Are Residential Habitation Facilities on The Site?
Yes
No
Evaluate For Presence of LBP in Residential Habitation (See Section 2)
Determine The Potential for Historical Pb Release- Collect Preliminary Samples if Warranted
Is LBP Present?
No
Consider No Further Action
No
Does Pb Level Exceed Background Levels? (See Sec. 3.1)
Yes
Yes
Do Pb Levels Exceed Risk Screening Levels? (See Section 3.2)
No
Yes
No
Is the Residential Housing Part of a DERP OU Investigated Under CERCLA?
Yes
Do Pb Levels Require a Lead Risk Assessment Under CERCLA?
Yes
Conduct Site-Specific Pb Risk Assessment Using One or More Pb Models ? (See Section 3.0)
No
Is Management of LBP Units Being Transferred to PPV?
No
Is the LBP Site Being Transferred as Real Property Under BRAC?
Consider No Further Action Or Remediate According to CERCLA Pb Risk Management Guidelines
Yes
Yes
Navy or PPV Must Conduct Title X Hazard Assessment of LBP Based on Year of Construction According to DON Memo (See Section 2.1)
Conduct Title X Hazard Assessment and Remediation of LBP Following LBP Field Guide and DOD Memo (See Section 2.2)

1.2 Human Health Risks Associated with Pb Exposure

The human health effects of excess lead exposure were first recognized in 1768 and have been extensively studied since. Advances in clinical diagnosis of lead exposure, biomonitoring, toxicology, and epidemiological studies have resulted in very sensitive tests to identify subtle cognitive and physiological changes resulting from low-level lead exposure in children (it should be stressed, however, that these low-level effects have been identified in exposed populations and not in individual children). For this reason, health threats to children and fetuses have been the primary focus of USEPA's risk assessment/management program. As part of this effort, USEPA (as well as some state regulatory agencies) has developed mathematical models to investigate health threats posed by lead at residential properties, as well as non-residential occupational sites where the risk assessment models are used to determine risks to children and to unborn fetuses, respectively. All lead models assume relatively long-term daily exposures where steady-state conditions develop between lead intake and elimination from the body. It should be noted that no predictive lead risk assessment model has yet been developed to evaluate the health risks associated with direct ingestion of leaded paint chips or other discreet forms of acute exposures to lead. Additionally, no lead model should be used to predict short or intermittent exposures to lead. For these types of exposures, a sample of blood must be taken and the actual level of lead must be measured directly.

Lead is ubiquitous in the environment, and all humans are exposed to lead from diverse sources on a daily basis. Lead is, by definition, not a "poison" because it is neither toxic nor lethal at low doses. According to the Centers for Disease Control and Prevention (CDC), the term "lead poisoning" is defined as a case in which a measured whole blood level of lead is found to be in excess of 50 micrograms per deciliter (µg/dL). However, a blood level of greater than 10 µg/dL in children is currently considered by CDC, the National Research Council (NRC)-National Academy of Sciences (NAS), and USEPA to be elevated and warranting risk mitigation steps to be taken. Consequently, health and risk management policies have been developed to prevent PbB levels from exceeding this "health-protective bright line."

Lead produces similar toxic effects in similar target organs in both children and adults; however, there are age-related differences in the dose-response relationship and sensitivity of the developing fetus and young children compared with adults. All exposure conditions being equal,

children are more susceptible to the toxic effects of lead when compared with adults, and some of these effects are irreversible in children. The reasons for the increased toxicity and particular focus on childhood exposure in lead risk assessment are as follows:

- Children have higher intake rates per unit body weight of environmental media (soil, dust, food, water, air, and paint), compared with adults;
- Children absorb a higher fraction of ingested lead from the gastrointestinal (GI) tract than do adults; and
- Children's developing nervous systems are uniquely sensitive and much more susceptible to lead-induced toxic effects than adults.

Over the last few decades, numerous toxicological and epidemiological studies have revealed subtle lead-induced health effects in infants and small children exposed to low levels of lead. These new highly sensitive diagnostic techniques, coupled with advances in analytical methods, have revealed that when blood levels exceed 10 mg/dL, impaired cognitive function, behavioral difficulties, and fetal organ development may be manifest. Of these effects, a decrease in cognitive function is regarded as the most quantifiable. It should be noted that, although PbB levels greater than 10 μg/dL are considered a threat to young children, the average PbB level among U.S. children is approximately 2 to 3 μg/dL, indicating there may be a low margin of safety associated with childhood lead exposure.

Overview of USEPA Lead Risk Management Policy

USEPA has developed risk management guidelines for classifying Pb risks that are predicted with USEPA Pb models at CERCLA and RCRA sites. They are as follows:

- PbB-related risks are based on the assumption that either a developing fetus or child will be exposed to site Pb conditions;
- A serum PbB level of 10 μg/dL is considered a bright line *in a child and in a fetus;*
- Baseline or background PbB levels (unrelated to site activities; i.e., regional sources from air, soil, dust, food, and water) are *added* to Pb levels directly associated with site-specific exposures.

The Center for Disease Control and Prevention (CDC) National Health and Nutrition Examination Surveys (NHANES) is an ongoing series of national examinations of the health and nutritional status of the civilian non-institutionalized population, have been the primary source for monitoring PbB levels in the U.S. population (CDC 1994). The findings in NHANES III indicate that the PbB levels for the U.S. population decreased by 22% (between 1970-1980 and 1991-94), and the prevalence of PbB levels above 10 μg/dL decreased by 51% over the same period. CDC has concluded that the dramatic decline in PbB levels in the U.S. population, particularly among children, since the late 1970s is primarily the result of the regulatory ban on leaded gasoline.

It is paramount to incorporate the latest information on decreasing U.S. PbB levels in all Navy risk assessments because background (or baseline) PbB levels are *added* to the contribution of lead that is associated with site-specific exposures. This is important because as long as the serum PbB level, which represents the *sum* of background and site-specific Pb exposures, remains below 10 μg/dL, there is no health concern. Therefore, allowable site-specific exposures can be increased concomitantly with a decrease in background or baseline levels. From a practical standpoint, this means that less remediation may be necessary at Navy Installations as baseline PbB levels continue to decrease throughout the United States.

Lead risk assessments (with very few exceptions) are always conducted under the assumption that either children or a developing fetus is the exposed receptor. That is, in contrast to a risk assessment for other chemicals where both childhood and adult risks are estimated, USEPA risk assessment/management policy mandates that current or potential exposures to young children be exclusively evaluated. This means even when both current and future exposures will be occupational, with adults the only receptor, it is assumed that a female worker will become pregnant and the fetus will become secondarily exposed by the mother's blood (via placental exchange).

1.3 Summary of Federal Lead Standards

USEPA

According to USEPA's (1998a) policy of addressing multimedia exposure to lead at residential sites, the Agency's statutory authority is limited. Multimedia exposure is defined as exposures occurring via contact with soil, ground water, airborne particulates, lead plumbing, interior dust, and interior and exterior leaded paint. While these sources of lead may contribute to total

exposure and need to be evaluated to predict PbB levels, USEPA recognizes that it may not have the authority to initiate remediation:

> *"However, there are limitations on the Agency's statutory authority under CERCLA to abate some of these sources, such as indoor leaded paint and lead plumbing, because CERCLA responses may be taken only to releases or threatened releases into the environment [CERCLA §104 (a)(3) and (4)]".*

USEPA's cleanup decisions are based upon both risk assessment and consideration of "applicable or relevant and appropriate requirements" (ARARS). There are potential limitations in CERCLA that may be relevant to lead contaminated sites. For example, Section 104(a)(3)(B) limits USEPA's ability to respond to releases within residential structures as follows:

> *"The President (EPA) shall not provide for removal or remedial action under this section in response to a release or threat of release . . . from products which are part of the structure of, and result in exposure within, residential buildings or business or community structures . . . "*

USEPA has also co-signed a memorandum of agreement with DOD (1999) regarding the manner in which LBP sites in residential areas will be investigated. According to the agreement, the framework in Title X will be applied to LBP sites except in limited circumstances. Further details are presented in Section 2.2.

Housing and Urban Development (HUD)

In 1992, Congress passed the *Housing and Community Development Act* (Public Law 102-550), which included Title X which is the *Residential Leaded Paint Hazard Reduction Act* (1992). Title X is a comprehensive law designed to direct the response to the public health problem of leaded paint hazards in residential housing. Title X contains all the regulatory requirements Navy project teams need to investigate Pb hazards at LBP sites and should be followed unless very unique circumstances exist at the site. For those sites NEHC can provide assistance on the best technical approach.

Title X also directed the Occupational Safety and Health Administration (OSHA) to increase the protection for workers exposed to lead hazards. Title X, by amending the Toxic Substances Control Act, directed the National Institute of Occupational Safety and Health (NIOSH) to:

> *"...conduct a comprehensive study of means to reduce hazardous occupational lead abatement exposures. This study shall include, at a minimum, each of the following— (A) Surveillance and intervention capability in the States to identify and prevent hazardous exposures to lead abatement workers. (B) Demonstration of lead abatement control methods and devices and work practices to identify and prevent hazardous lead exposures in the workplace. (C) Evaluation, in consultation with the National Institute of Environmental Health Sciences, of health effects of low and high levels of occupational lead exposures on reproductive, neurological, renal, and cardiovascular health. (D) Identification of high-risk occupational settings to which prevention activities and resources should be targeted. (E) A study assessing the potential exposures and risks from lead to janitorial and custodial workers."*

Federal Standards

The following is an abbreviated list of pertinent federal standards:

LBP : CDC defines *"leaded paint"* as paint containing lead in excess of 1.0 mg/cm^2 or 5,000 mg/g (0.5%). Hazardous conditions for leaded paint include the following:

- Paint that is peeling, flaking, chipping, or chalking;
- Paint areas subject to friction or abrasion;
- Paint with the possibility of being chewed; and
- Paint areas undergoing renovation.

Highest priority is housing built before 1950. Next-highest priority is housing built between 1950 and 1978. (Residential paint containing up to 50% lead was in widespread use through the 1940s; lead use in residential paint declined thereafter and was banned in 1978.)

Dust Lead: Guidelines from the Department of Housing and Urban Development (HUD) recommend that the following interior house dust lead levels (determined by wipe sampling) be used for risk assessment:

- 100 micrograms per square foot (µg/ft^2) for carpeted or uncarpeted floors;
- 500 µg/ft^2 for window sills; and

- 800 μg/ft^2 for window wells (or window troughs).

Lead dust is most likely to be hazardous to children because of the potential for ingestion when it is on surfaces with which children or their toys have frequent direct contact.

Soil Lead: Interim USEPA guidelines call for exposure-reduction activities (e.g., using ground cover to create a barrier over contaminated soil) when lead levels in bare residential soil are between 400 and 5,000 parts per million (ppm). Permanent abatement (e.g., removal and replacement) of bare residential soil is recommended when lead concentrations exceed 5,000 ppm. The HUD guidelines set exterior dust lead levels in excess of 800 μg/ft^2 as a lead hazard. Soil lead is highest around foundations of older homes that have been painted with exterior leaded paint and around homes adjacent to heavily trafficked roadways.

Airborne Lead: OSHA has determined that occupational exposures to lead concentrations greater than 50 μg/m^3 for an 8-hour time-weighted day pose a hazard to workers. This concentration is the permissible exposure limit.

Elevated PbB levels: CDC requires environmental intervention for children who have PbB levels greater than 20 μg/dL or PbB levels of 15 to 19 μg/dL in two consecutive blood samples taken several months apart.

2.0 INVESTIGATING NAVY REAL ESTATE PROPERTY CONTAINING LBP

2.1 Background

The Navy will most often investigate the two following types of Navy sites that may contain LBP:

- Navy Family Residential Housing Transferring Management to a Public/Private Venture; or
- Family Residential Housing Transferring Real Estate Property to Public/Private Venture

The Navy has developed specific guidance based on Title X, which provides the regulatory framework for investigating and remediating these sites. Except in very rare and unique circumstances Navy guidance should be followed exclusively. USEPA and DOD have agreed that CERCLA/RCRA do not apply at LBP sites and should not be used as the framework for investigations.

Unlike residential housing, no Navy guidance has been developed for non-residential areas (i.e. communication towers, water towers, bridges etc.). However, USEPA and DOD (1999) have agreed that that non-residential areas would only require only limited sampling. Further guidance can be provided by NEHC.

The following sections provide an overview of Navy guidance for residential units undergoing transfer.

2.2 Navy Family Residential Housing Transferring Management to a PPV

The policy for transferring management of Navy LBP family housing to a PPV is detailed in a DON (2004) memo. A PPV is defined as a nongovernmental entity that accepts and manages the military family housing. The main goal of the policy is to minimize or eliminate LBP hazards in compliance with:

a. Title X,

b. 24 C.F.R. Part 35 (or HUD Regulations), and

c. 40 C.F.R. § 745.227.

There are two categories of family housing based on year of construction, namely, housing built before 1960 and housing built between 1960 and 1978.

For military family housing constructed before 1960, the following Navy guidelines apply:

a. If the military family housing is occupied when transferred to the PPV Partner, the PPV Partnership Agreement shall require the PPV Partner to abate identified LBP hazards in the family housing and associated property in accordance with regulations (a) through (c) no later than the first change of occupancy or during renovation/replacement, whichever event occurs first. The LBP Management Plan for such housing shall identify the steps that the PPV Partner will take to address any identified LBP hazards in the housing and associated property that pose an immediate threat to the health of military family housing residents.

b. If the military family housing is vacant when transferred to the PPV Partner, the PPV Partnership Agreement shall require the PPV Partner to abate any identified LBP hazard in accordance with references (a) through (c) before occupancy.

c. If DON elects to abate LBP hazards in military family housing before transferring it to the PPV Partner, the DON must undertake such abatement in accordance with references (a) through (c).

For military family housing constructed between 1960 and 1978, the following Navy guidelines apply:

a. The DON must conduct an inspection and, if required, a Lead Risk Assessment that meets the work practice and certification standards set forth in reference (c) and provide the results to the PPB Partner before conveying the military family housing.

b. The PPV Partnership Agreement shall require the PPV Partner to maintain the family housing and associated property in accordance with a Lead Management Plan.

c. The PPV Partnership Agreement shall require the PPV Partner to take appropriate corrective action in any military family housing unit covered by the PPV Partnership if

the PPV Partner is advised that a child under six, living in the unit, has been reported to have an elevated blood lead level (EBL) and the unit has been identified as the potential source.

In addition, the memo requires the PPV Partner to comply with all Federal, state, interstate and local requirements respecting LBP and LBP hazards. State requirements may necessitate LBP hazard treatment and/or abatement before occupancy of rental units. It should be stressed that this Navy policy does *not* apply to transfer of military family housing under the Base Closure and Realignment Act or property disposal actions for any purpose other than a PPV.

Housing that is unoccupied for demolition does

2.3 Family Residential Housing Transferring Real Estate Property to Public/Private Venture

The transfer of residential real property should be carried according to: *LBP Guidelines for Disposal Of Department of Defense Residential Real Property-A Field Guide.* Interim Final December 1999, which represents a collaborative effort between USEPA and DOD. This section is based on excerpts from the field guide. For additional information the field guide should be reviewed.

The regulations used to address LBP are the requirements contained in Title X. However, "Title X", includes the implementing regulations under TSCA Section 403 and HUD Section 1012/1013. USEPA and DOD agreed that for the majority of situations involving target housing, Title X is sufficiently protective to address the hazards posed by LBP which as part of a Memorandum of Agreement between DoD and USEPA. This agreement concluded that Title X Title X-TSCA procedures provide an efficient, effective, and legally adequate framework for addressing LBP in residential areas and that CERCLA/RCRA will not be applied except in limited circumstances. DoD also agreed to abate 1960-1978 target housing (as defined in Title X) with LBP hazards where a risk is indicated, or to otherwise ensure that such structures will not be used as target housing until such abatement is performed by either DoD or the grantee (PPV). Additionally, when DoD installations comply with jointly developed guidelines, EPA agreed it will review the Finding of Suitability to Transfer (FOST) without adverse comments regarding LBP.

For federally-owned residential real property subject to property transfer, Section 1013 of Title X (42 U.S.C. 4822) requires:

- The inspection, risk assessment, and abatement of LBP hazards in target housing constructed prior to 1960;
- The inspection and risk assessment for target housing3 constructed between 1960 and 1978;

The regulation implementing Section 1013 of Title X, 24 CFR 35, was issued as a final rule on 15 September 1999 (64 FR 50140). Subparts of the regulation applicable to federally owned facilities are Subparts A, B, C, and R, and include the following requirements:

- LBP inspections and risk assessments must be performed for all target housing prior to sale/transfer;
- Risk assessments must be performed within 12 months of the date of transfer, and any abatement required must be conducted no later than 12 months after the completion of the risk assessment;
- The responsibility for abatement may be assumed by the transferee through the transfer agreement.

The Field Guide contains a number of requirements that exceed current federal regulations including:

- Soil-lead hazards surrounding target housing constructed between 1960 and 1978 will be abated. The purchaser may be required to perform the soil abatement as part of the transfer agreement.
- Potential soil-lead hazards (bare soils with lead concentrations between 400-2000 ppm (excluding children's play areas4)), will be evaluated for the need for abatement, interim controls or no action; the level of action will be determined by the LBP risk assessment.
- Child-occupied facilities (day care centers, preschools, and kindergarten classrooms visited regularly by children under 6 years of age) located on residential real property that will be reused as child-occupied facilities following transfer will be evaluated for LBP

hazards. Hazards identified will be abated by the transferee prior to use as a child-occupied facility;

- Target housing that will be demolished and redeveloped as residential real property following transfer will be evaluated by the transferee for soil-lead hazards after demolition of the existing target housing units. Abatement of any soil-lead hazards will be conducted by the transferee prior to occupancy of any newly constructed dwellings.

These requirements expand the application of Title X requirements to include child occupied facilities providing an added measure of protection for children. The Field Guide also extends Title X abatement requirements to soil- lead hazards surrounding housing constructed between 1960 and 1978, ensuring that all soil-lead hazards are abated regardless of the age of the housing.

Exhibit 2 presents the applicability of Title X. It should be noted that while "isolated" LBP sites will be transferred based on Title X, CERCLA/RCRA should be applied when the LBP property is part of a Defense Environmental Restoration Program (DERP) Site. Exhibit 3 presents the applicability of Title X of the residential LBP hazard reduction act.

EXHIBIT 2
APPLICABILITY OF TITLE X

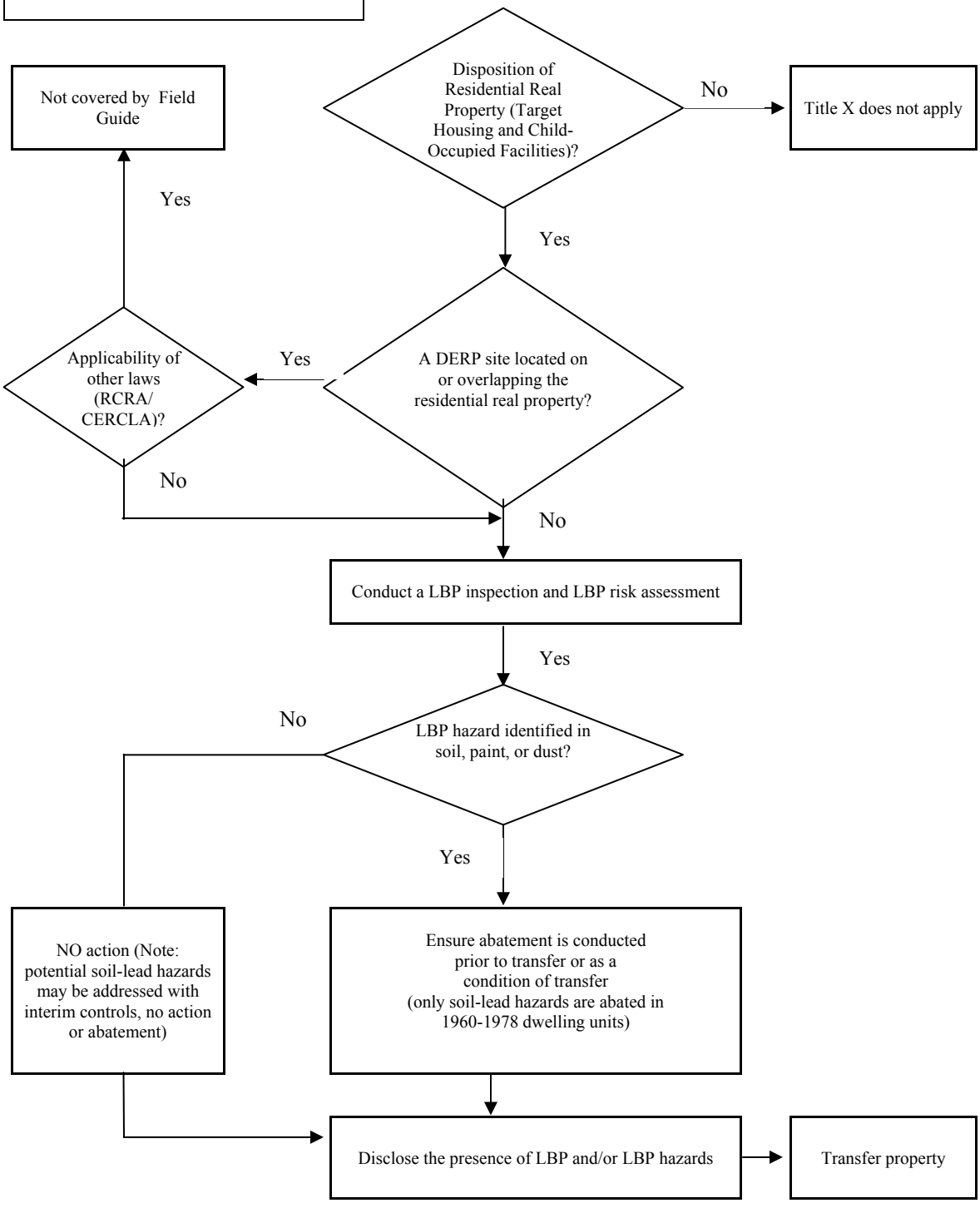
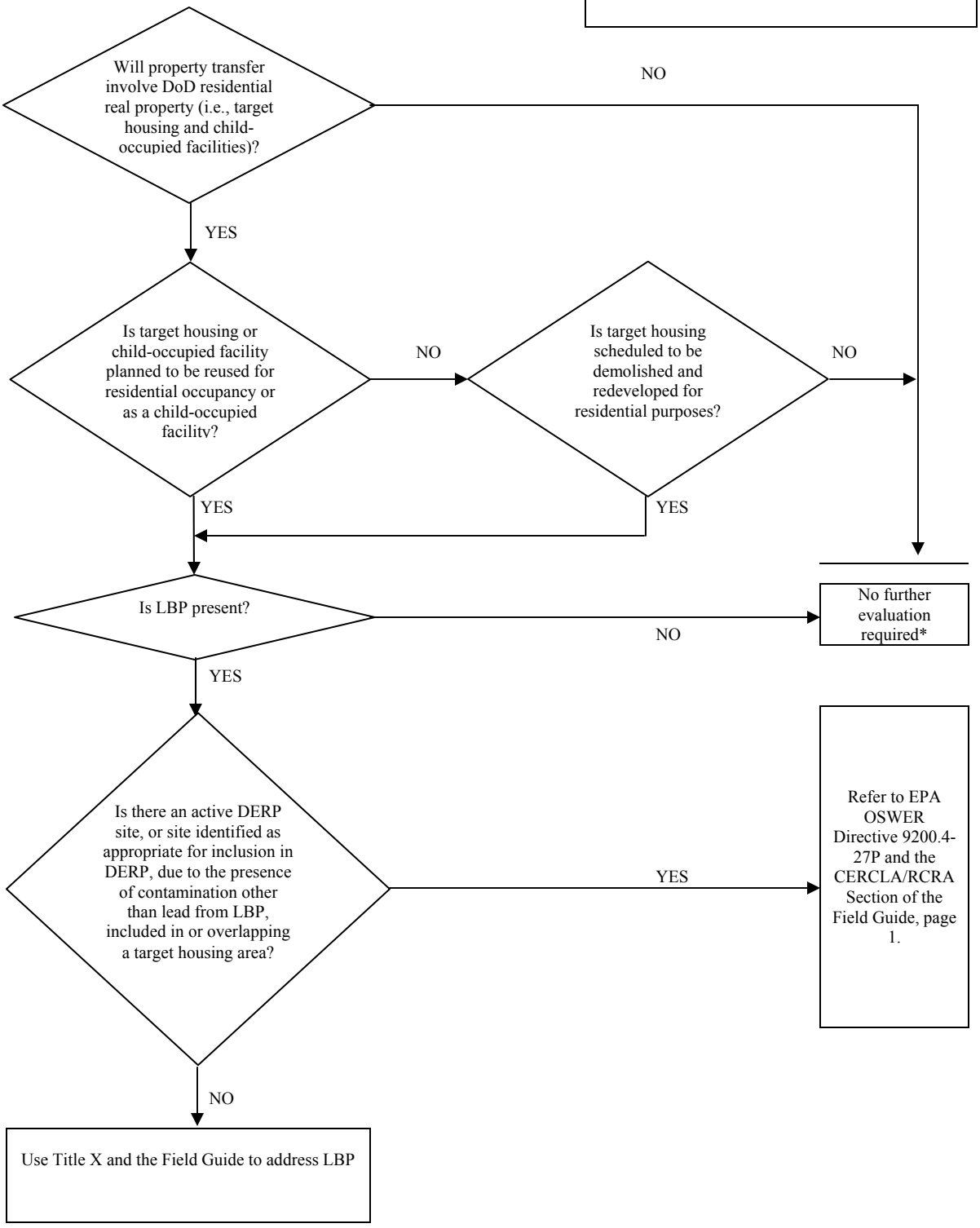


EXHIBIT 3
APPLICABILITY OF TITLE X OF THE RESIDENTIAL LBP HAZARD REDUCTION ACT



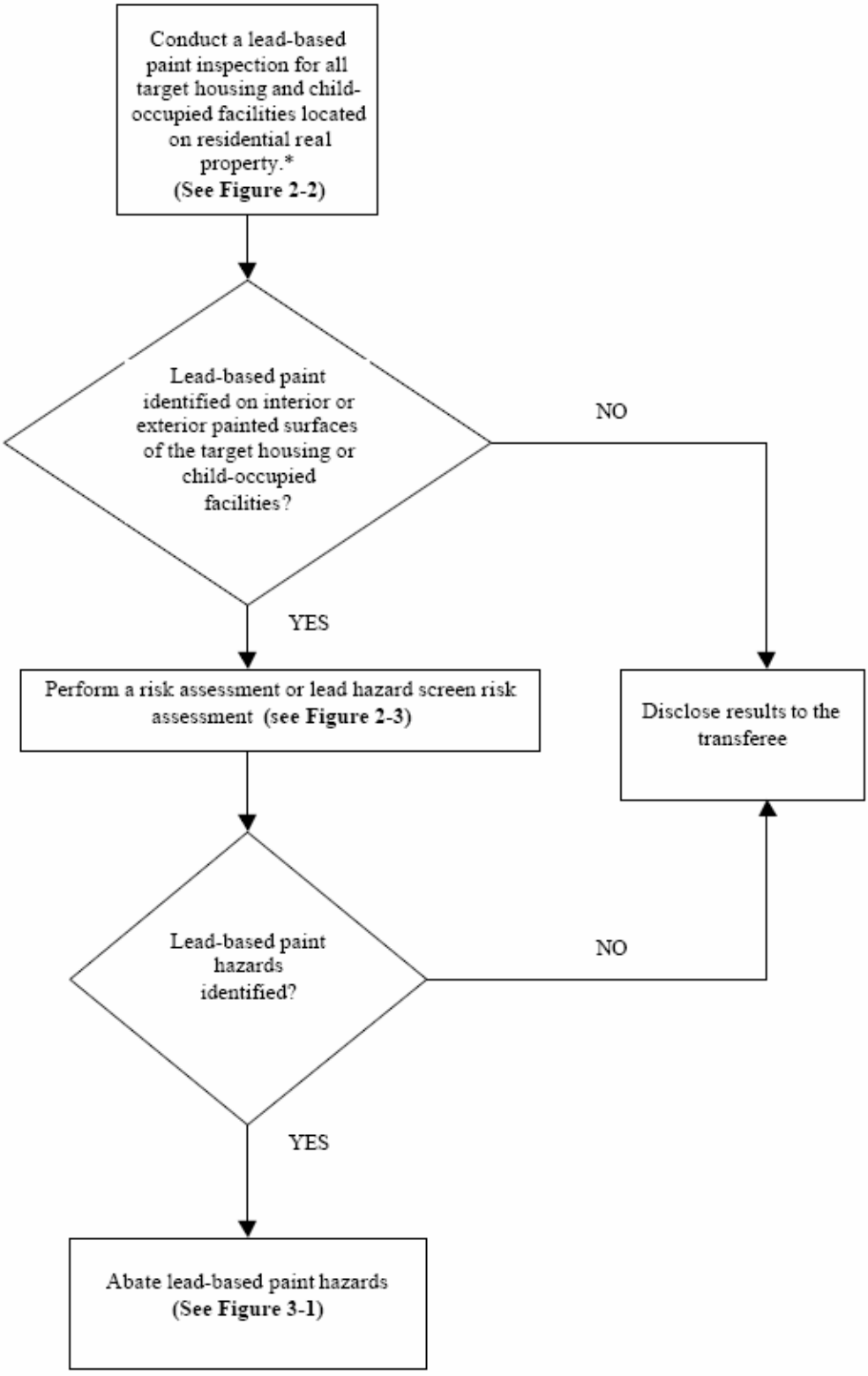
The Field Guide LBP requirements are only applicable to circumstances involving the transfer of DoD residential real property. Affected residential real property includes: child-occupied facilities located on residential real property, target housing, and target housing planned to be demolished following transfer and redeveloped for residential use. The requirements contained in the Field Guide do not apply to the following types of property:

- Property not scheduled to be transferred;
- Structures not contained within the definition of residential real property. Residential real property does not include schools, shopping malls, churches, barracks, or other nonresidential structures;
- Residential dwellings constructed after 1 January 1978;
- Housing designated exclusively for the elderly or persons with disabilities (unless a child younger than 6 years of age also resides, or is expected to reside in such housing) or any zero-bedroom dwelling (such as barracks);
- Leased property or other property not subject to disposition;
- Residential real property not intended for residential occupancy or use as a child occupied facility following transfer; and
- Residential real property included in transfer agreements executed prior to the effective date of the DoD LBP Policy for Disposal of Residential Real Property. Services must still meet any promulgated regulatory requirements applicable to the disposition of real property in effect on the date of the disposition of the property.

LBP Evaluation

The term evaluation means an inspection and a risk assessment and can also include a lead-hazard screen, paint testing, or a combination of these to determine the presence of LBP hazards or LBP. The LBP inspection is used to establish the presence or absence of LBP on interior and exterior surfaces. The risk assessment is conducted to assess whether painted surfaces, dusts, and soils represent LBP hazards and recommend options for hazard abatement. The LBP evaluation process is presented in Exhibit 4.

EXHIBIT 4
LBP EVALUATION PROCESS

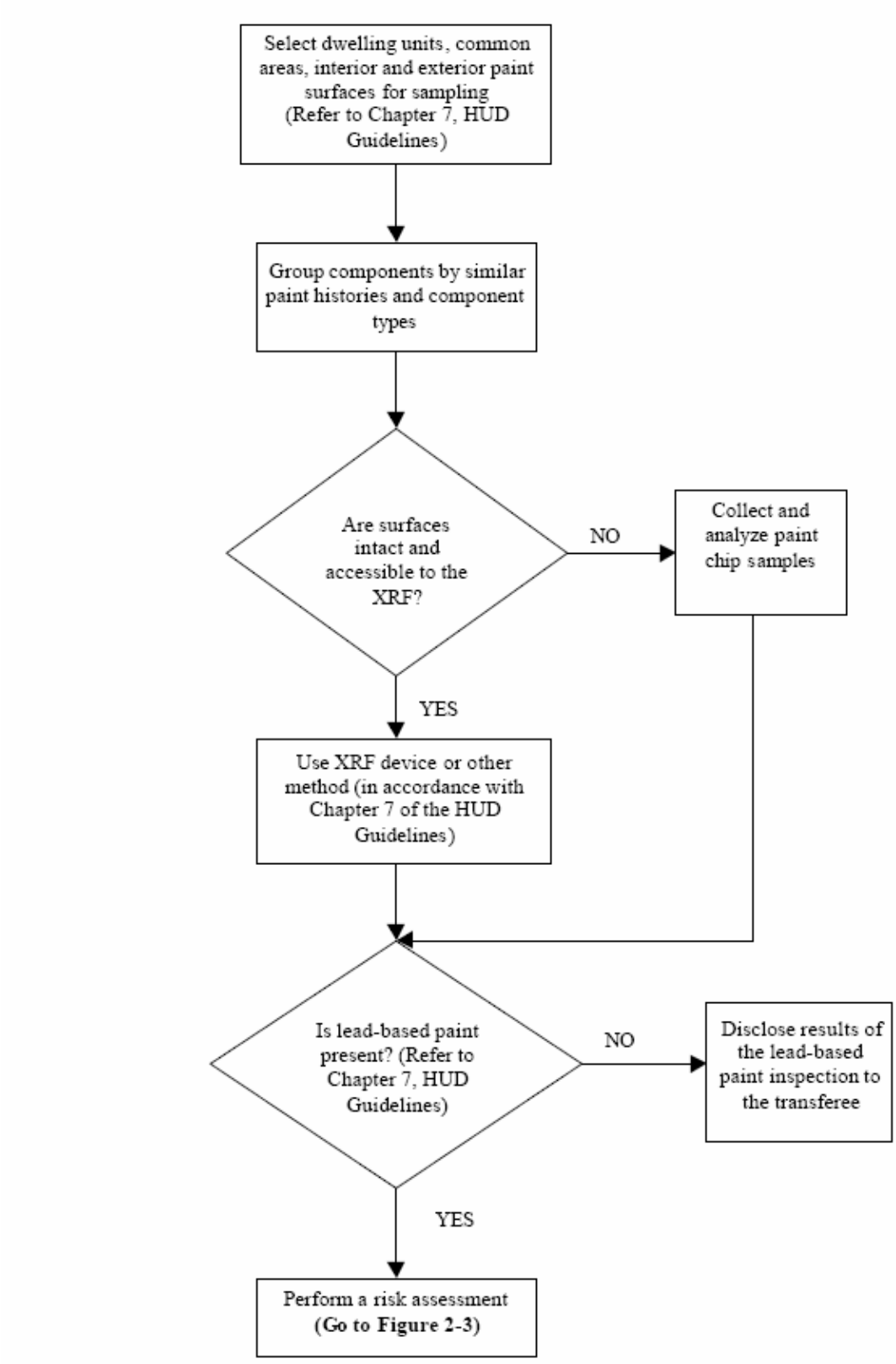


LBP Inspection

An inspection for LBP is a surface-by-surface investigation to determine the presence of LBP and the provision of a report explaining the results of the investigation. 24 CFR 35, Subpart C and DoD policy requires that a LBP inspection be performed for all target housing and child-occupied facilities located on residential real property. 40 CFR Part 745, Subpart L requires that LBP inspections be performed by a certified inspector and in accordance with the procedures contained in 40 CFR 745.227 and Chapter 7 of the HUD Guidelines, (revised September 1997).

An inspection is used to inventory the painted surfaces of the interior and exterior of a dwelling unit. The inventory involves testing of all of the "testing combinations," which are distinct combinations of building components, substrates, and locations (room, hallway, exterior, etc.). (Because of their large area, at least four walls are tested in each room or room equivalent.) The inspector is responsible for characterizing the distinct components for which testing may be required. Certain adjacent building components that are not likely to have different painting histories can be grouped together in a single testing combination. For multi-family housing with similarly constructed dwelling units, the inspector will select units, common areas, and exterior areas for testing to represent conditions in all units and common areas, in accordance with the sampling strategy provided in the HUD Guidelines. The LBP inspection process is presented in Exhibit 5.

EXHIBIT 5
LBP INSPECTION PROCESS



Risk Assessment

A "risk assessment" for LBP sites is very different from a conventional risk assessment. For example, no scientific effort is made to predict or model levels in the blood of children or adult which are then typically compared to toxic levels. Rather, an LBP risk assessment is an on-site investigation to determine and report the existence, nature, severity, and location of LBP hazards in residential dwellings. The risk assessment can be a separate study performed after LBP inspection, a lead hazard screen assessment, or may be combined with the LBP inspection. An EPA certified risk assessor or an individual certified by an authorized state program must conduct the risk assessment. A lead hazard screen risk assessment may be appropriate if, based on-site history and other features; the residential dwelling is unlikely to contain LBP hazards. The lead hazard screen usually involves limited paint and dust sampling but can also include soil sampling. If no LBP hazards are identified during the lead hazard screen risk assessment, no further action is required. However, if LBP hazards are found or are suspected to be present, a full risk assessment should be performed to define specific surfaces/media requiring abatement. The sampling results from the lead hazard screen may be used to supplement sampling required for the risk assessment. The evaluation and reporting process for the lead hazard screen risk assessment consists of the following steps:

- An evaluation of the history and background of the target housing or child-occupied facility, including a review of available information on the age and history of the structures, occupancy by children under the age of six, and the physical characteristics of the building;

- A visual inspection to determine the presence, location, and extent of deteriorated paint and other LBP hazards. The visual inspection also includes an assessment of probable use patterns that could result in exposure to LBP;

- Sampling of paint, dust, and soil media;

    - Testing of each deteriorated painted surface with a distinct painting history that has been identified as containing LBP. The LBP inspection should be consulted in determining the need for any additional painted surface samples. Either the XRF or paint chip sampling may be used to evaluate painted surfaces. All paint chip, dust, and soil samples must be analyzed by laboratories recognized by EPA through the NLLAP as described in 40 CFR 745.227(f)(2).

- Collection of dust wipe samples, either composite or single surface samples, from interior windowsills and floors in all living areas where young children are most likely to come into contact with dust. Dust wipe samples should be collected from windowsills and floors in all living areas where one or more children, age 6 and under, are most likely to come into contact with dust. For multi-family property dwellings and child-occupied facilities dust samples should also be collected from windows and floors in common areas.

- Collection of composite soil samples from the first ½ inch of soil from the drip-line/foundation and the mid-yard areas where bare soil is present. Composite sampling procedures requirements include.

    - Two composite samples collected from bare soil areas in the mid-yard and drip-line respectively. Each composite sample is made up of two or more sub-samples but not to exceed 10 sub-samples.

    - Separate composite samples collected from bare soils in children's play areas.

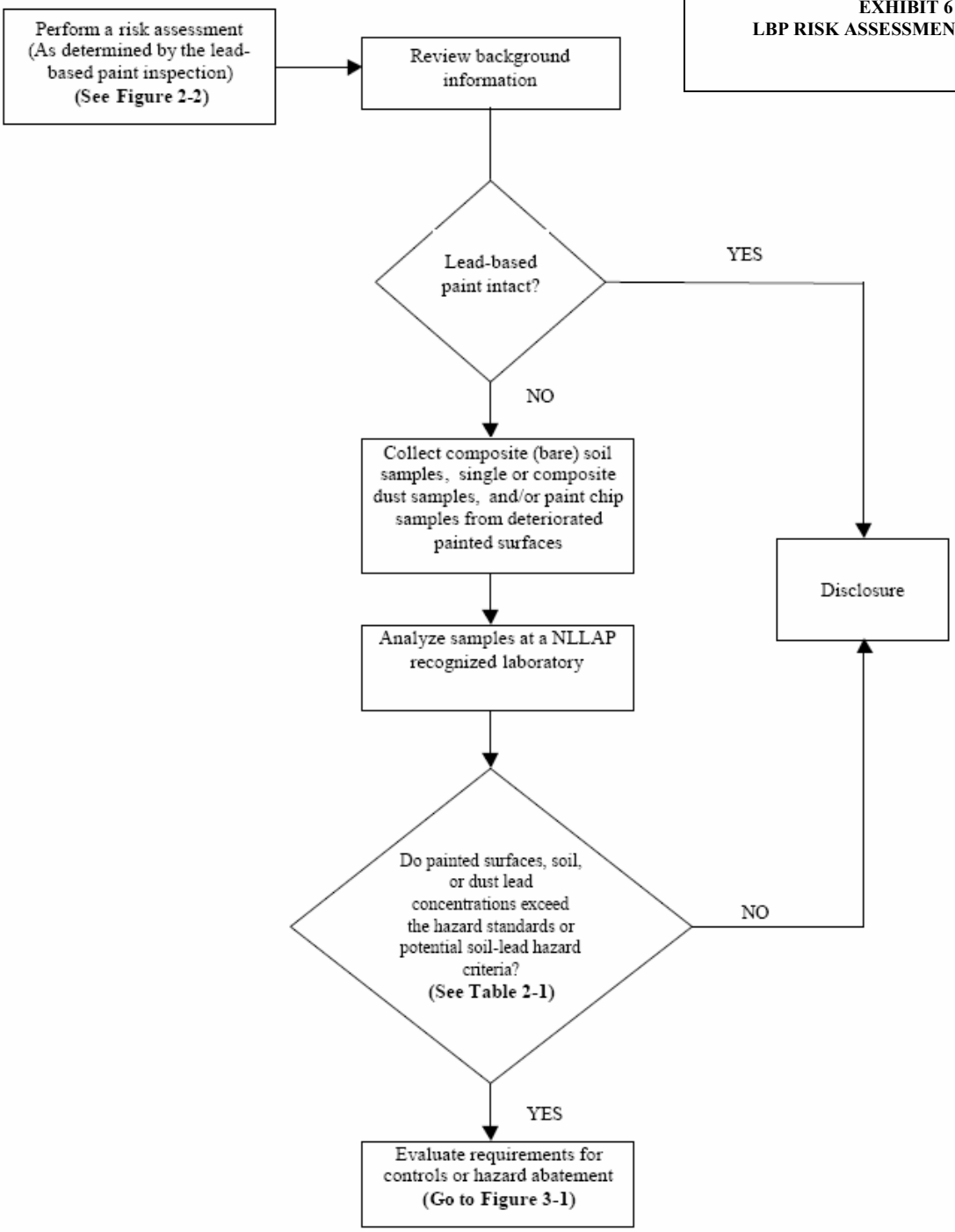
The arithmetic mean, or the average of the composite samples, is used to define a yard-wide average of soil lead concentrations. If the arithmetic mean of the composite samples is equal to or exceeds the hazard standard of 2,000 ppm in bare soils (bare soil areas must exceed 9 square feet) or 400 ppm in children's play areas, additional sampling may be required to define the extent of soil requiring abatement. The results of the mid-yard or drip-line composite sampling may be used to target areas of bare soils for additional sampling. For target housing scheduled to be demolished and redeveloped for residential use after transfer, the transferee will be responsible for evaluating and abating any soil-lead hazards. The transfer agreement should specify that soil sampling be conducted after demolition and removal of demolition debris and prior to occupancy of any newly constructed dwelling units in a manner consistent with Title X and the HUD guidelines.

- Evaluation of all sampling data, background information, findings from the visual assessment, and management and maintenance information against LBP hazard criteria. to determine the presence or likelihood of exposure by children to LBP hazards in dusts, soils, painted surfaces and potential hazards in soils (soil lead concentrations between 400 and 2,000 ppm, excluding children's play areas).

- Preparation of a risk assessment report documenting all sampling data, related LBP hazards, and recommended options for control and/or hazard abatement.

The risk assessment may use several different sampling strategies for multi-family dwellings, including targeted, worst-case, or random sampling of dwelling units for housing with five or more dwelling units.. The facility should select a sampling strategy on the basis of the desired degree of confidence, economic factors, and the availability of historical construction and maintenance records, in accordance with the HUD Guidelines or other documented EPA methodologies. If the condition of painted surfaces and concentrations of lead in paint and other media do not exceed the hazard criteria as either a LBP hazard or a potential hazard, then no further action is required. Identified LBP hazards must be abated. Potential soil- lead hazards may be addressed through interim controls, no action, or abatement. Exhibit 6 presents an outline of the risk assessment process.

EXHIBIT 6
LBP RISK ASSESSMENT PROCESS



LBP Hazard Criteria

LBP hazards and hazard criteria, are defined by 24 CFR 35, Subpart R and DoD policy, for all three sources; painted surfaces (including accessible, friction, and impact surfaces), dusts, and soils, as they apply to target housing and child-occupied facilities.

- ***Deteriorated Painted Surfaces***. Painted surfaces must meet two conditions to be considered LBP hazards: the paint film must contain LBP and the surface must be deteriorated. Intact surfaces containing LBP are not considered LBP hazards and thus do not require abatement.

- ***Chewable (Accessible), Friction, and Impact Surfaces.*** Accessible, friction, and impact surfaces are a special class of painted surfaces with slightly different hazard assessment criteria. A friction surface is an interior or exterior surface that is subject to abrasion or friction, including certain window, floor, and stair surfaces. An impact surface is an interior or exterior surface that is subject to damage by repeated impacts from related building components, for example, certain parts of doorframes. A chewable or accessible surface is an interior or exterior surface painted with LBP that is accessible to a young child to mouth or chew. Friction surfaces are considered a LBP hazard if all of the following three criteria are satisfied: the surface contains LBP, there is a dust lead hazard present on the nearest horizontal surface underneath the friction surface, and the surface is subject to abrasion. An impact surface is a LBP hazard if there is LBP present, paint on the impact surface is deteriorated or damaged, and the damaged paint is caused by impact with a related building component. LBP hazards identified on friction or impact surfaces must be abated. An accessible surface is a LBP hazard if the painted surface shows evidence of teeth marks. If an accessible surface is a LBP hazard, only the component bearing that surface should be abated. If no teeth marks are evident, the surface is considered to be intact and is not a LBP hazard.

- ***Dusts.*** LBP hazard criteria for dusts or dust-lead hazards are defined for carpeted and uncarpeted floors and interior windowsills on the basis of either single surface or composite dust samples. If the floor and window sill composite or single surface dust wipe sample concentrations from any given room or common area exceeds 40 mg/ft2 on uncarpeted and carpeted floors or 250 mg/ft2 on interior window sills, dusts in that room or common area represent a LBP hazard, and the source of the dust should be identified

and controlled.

- ***Soils.*** A soil-lead hazard is a concentration of lead in a composite soil sample greater than or equal to 400 ppm in bare soils in children's play areas, or greater than or equal to 1200 ppm in bare soil areas other than children's play areas based on a yard-wide arithmetic mean of composite samples. DoD defines a potential soil-lead hazard as concentrations of lead in bare soil areas surrounding a dwelling unit that are greater than or equal to 400 ppm and less than 1200 ppm. As a matter of policy, services may undertake measures to address potential soil lead hazards such as abatement or interim controls, or determine that no action is appropriate based on the LBP inspection and risk assessment. In evaluating each of these alternatives the risk assessor should consider the relative proximity of children's play areas, the potential for dust generation and the areal extent of bare soil available for exposure, state and local requirements, as well as the feasibility of any potential control options. Potential soil-lead hazards do not include children's play areas and are not defined for metal structures.

LBP Control and Hazard Abatement Measures

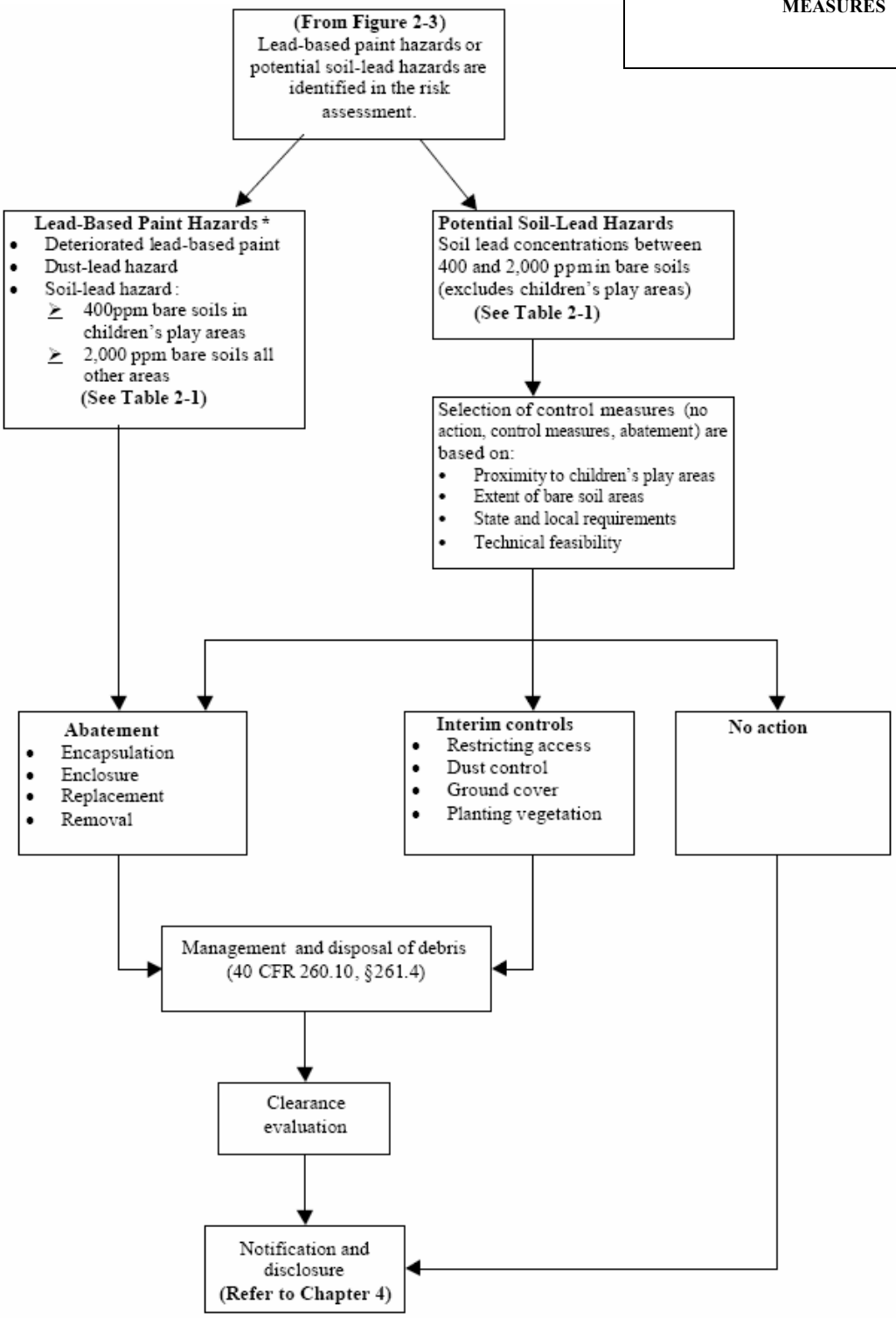
Title X requirements for control or abatement of LBP hazards differ depending on the age of the housing. 24 CFR 35, Subpart C requires abatement of LBP hazards identified in target housing constructed before 1960. For target housing constructed between 1960 and 1977, the regulation requires that the presence of any known LBP and/or LBP hazards be disclosed to the transferee of the property, but does not require abatement or control of LBP and/or lead-based hazards. The abatement must be conducted no later than 12 months after the risk assessment is completed and may be implemented prior to disposition of the property or may be made a condition of the property transfer. Interim controls may not be used to address LBP hazards required to be abated under 24 CFR 35, Subpart C and are regarded an optional treatment used at the discretion of federal agencies for LBP hazards identified in target housing constructed between 1960 and 1978 or conditions representing less than a LBP hazard.

As a matter of policy, DoD also requires that LBP hazards be abated in child occupied facilities, soil-lead hazards surrounding housing constructed between 1960 and 1978, and soil-lead hazards remaining after target housing has been demolished and redeveloped for residential use. The abatement must be conducted within 12 months after completion of the risk assessment, and DoD prefers that abatement be made a condition of transfer, in which case the services must ensure

that the transferee carries out the abatement prior to occupancy or sale. DoD policy also allows for either interim controls, no action, or abatement to be used to address potential soil-lead hazards (concentrations of lead in bare soil between 400 and 1200 ppm, excluding children's play areas), depending on the presence and likelihood of exposure to children.

After LBP control and hazard abatement measures have been completed, affected structures must undergo a clearance examination to ensure that all abatement activities have been conducted properly. The transferee will usually perform clearance examinations since most control and hazard abatement activities will be carried out following transfer. In such cases, requirements for control, abatement, and clearance activities must be included in the contract for sale or transfer agreement. In many cases, there are specific state and local regulations that must be considered in the design and implementation of any LBP abatement or control activity. It is important to consult with state and local agencies before initiating any control or abatement actions.

EXHIBIT 7
CONTROL AND HAZARD ABATEMENT MEASURES



Control Measures

Title X defines control measures [interim controls] as "a set of measures designed to reduce temporarily human exposure or likely exposure to lead-based paint hazards, including specialized cleaning, repairs, maintenance, painting, temporary containment, ongoing monitoring of lead-based paint hazards or potential hazards, and the establishment and operation of management and resident education programs." Control measures can be used to reduce or temporarily eliminate the potential for children to develop adverse health effects from exposure to potential soil-lead hazards. Control measures can be appropriate for bare soils with an average soil lead concentration between 400 and 1200 ppm, which are not used as a children's play area. Risk factors to consider in selecting control measures would be the proximity and the extent of bare soils available for exposure by children in nearby play areas. Non-risk factors include promulgated state and local requirements, as well as the technical feasibility of implementing any control measures. Soil that is adequately covered with vegetation, paving, or other landscape material should not generally require either control or abatement actions. State and local authorities should be contacted to identify additional requirements that should be considered for control measures. Control measures for potential soil-lead hazards can include planting grass or ground cover, mulch, or restricting access, and should be selected on the basis of both risk and non-risk factors. The basic elements of control measures include planning; implementation of controls, cleanup, clearance, and any ongoing maintenance and monitoring required to be performed by the transferee. The lead-based paint hazard control plan, prepared by the risk assessor, should identify any feasible control options that may be implemented to address potential soil-lead hazards

Abatement

Title X defines **abatement** as any set of measures designed to permanently eliminate lead-based paint hazards. EPA and HUD consider permanent measures as those that last at least 20 years. Under this definition, abatement includes removal of lead-based paint and dust-lead hazards, enclosure or encapsulation of lead-based paint, replacement of lead-painted components or fixtures, removal or permanently covering of lead-contaminated soil, and all preparation, cleanup, disposal, and post-abatement clearance testing activities associated with such measures. Abatement does not include renovation, remodeling, landscaping, or other activities when such

activities are not designed to permanently eliminate lead-based paint hazards but instead are designed to repair, restore, or remodel a given structure or dwelling. Even though these activities may incidentally result in the reduction or elimination of lead-based paint hazards, they are not considered abatement. Abatement also does not include control measures, operation and maintenance activities, and other measures designed to temporarily reduce lead-based paint hazards.

Disposal

Building debris and wastes from lead-based paint abatement activities may result in the generation of hazardous wastes. Transferees conducting these activities will be responsible for complying with all applicable disposal requirements. Transferees, Federal facilities (if applicable), and the contractors involved in abatement or control actions may be considered waste generators and must comply with the existing regulations outlined in RCRA, Subtitles C and D. Facilities should also identify any state and local regulations applicable to the treatment, storage, and disposal of lead-based paint abatement wastes. Currently, RCRA requires that wastes from abatement and control activities be tested to determine whether the material is a characteristic waste requiring special handling and disposal requirements as a hazardous waste. If the individual or entity responsible for abatement (generator) produces more than 100 kg of hazardous waste per month, the generator must comply with the RCRA hazardous waste regulations. Hazardous wastes staged on site during abatement activities may be stored either until abatement work is completed or until sufficient waste has been collected to constitute a load or shipment; however, storage (particularly storage over 90 days for which a storage permit is required) and disposal must be managed in accordance with RCRA regulations. If hazardous waste from a single generator is produced in small quantities (less than 100 kg of hazardous waste per month), it could be excluded as “conditionally exempt” through a small-quantity-generator exemption under 40 CFR §261.4. Nonhazardous or exempt wastes may be managed as solid waste with disposal in a state-licensed or state-permitted solid waste facility.

3.0 INVESTIGATING CERLA AND RCRA SITES WITH PB RISK ASSESSMENTS MODELS

3.1 Overview of Lead Risk Assessment Models

Lead occupies a unique position within USEPA risk assessment guidance and policy. While all other hazardous chemicals commonly detected in the Navy's Environmental Restoration Program are evaluated on the basis of chemical-specific toxicity factors (presented in USEPA's Integrated Risk Information System; IRIS), the health risks from lead are evaluated based on the predicted or directly measured concentration in the blood. That is, the concentration of lead in whole blood is used as a biomarker to assess potential risk to an individual. In contrast, risks are estimated for all other environmental contaminants as the probability of increased cancer risk or the potential for noncarcinogenic systemic effects based simply on chemical intake. This SOP presents guidance for using several lead risk assessment models to predict PbB levels associated with exposure to lead.

Although, in theory, it is possible to evaluate risk associated with lead exposure at any site by simply collecting blood samples in order to directly measure PbB levels in human receptors, for most sites, this is impractical or impossible. At some sites, it may be too time consuming or costly to conduct biomonitoring, while at others there may be no current lead exposures (or those who are exposed may not be willing to provide a blood sample). Nevertheless, empirical measurements of actual site-specific PbB levels are always preferable for determining whether a current health problem exists.

In cases where it is impractical or impossible to measure PbB levels, the only alternative may be to use a mathematical model to *predict* PbB levels to evaluate potential lead risks. Several mathematical models using different scientific approaches have been developed to predict risks associated with lead exposure. Depending on the type of site and the target exposed population; models are available to predict PbB levels for:

- Fetal and neonatal exposures;
- Childhood exposures (0 to 64 months of age);
- Adult resident; and

- Occupational worker.

The following lead models are used for risk assessment and risk management purposes:

- The USEPA *Integrated Exposure Uptake Biokinetic* (*IEUBK*) Model;
- The USEPA *Adult Lead* (*AL*) Model;
- California DTSC California LeadSpread (Ca*LS)* Model; and
- USEPA Region 8, *Integrated Stochastic Exposure* (*ISE*) Model.

The common element among these models is that they all yield predicted PbB levels based on the type of activities assumed during the exposure assessment. The results yielded by the models are then compared to acceptable PbB levels, and a determination is made as to whether remediation or intervention is warranted.

3.2 Choosing the Correct Lead Risk Assessment Model

Choosing the correct lead model for the Navy installation under investigation depends on the site conceptual model regarding potential current and future human receptors. While it is usually relatively easy to identify currently exposed populations, a qualitative or quantitative future land use analysis will be required to identify the most likely future receptors. Once current and future receptors are identified, choosing the correct model is simply a matter of selecting the risk assessment model that will predict PbB levels for that receptor. A summary of the lead risk assessment models and the primary receptor for the various models is presented in Exhibit 8, together with information as to whether the models have been verified or tested with empirical data as measured in blood samples of exposed individuals

EXHIBIT 8
SUMMARY OF VARIOUS LEAD RISK ASSESSMENT MODELS

	PRIMARY RECEPTOR (1)				
RISK ASSESSMENT MODEL	**FETUS**	**CHILD**	**ADULT RESIDENT**	**OCCUPATIONAL**	**VALIDATION STUDIES? (2)**
***IEUBK* (USEPA)**	**NO**	**YES**	**NO**	**NO**	**YES**
***ISE* (USEPA REGION 8)**	**NO**	**YES**	**NO**	**NO**	**YES**
***AL* (USEPA)**	**YES**	**NO**	**NO (3)**	**NO (3)**	**NO**
Ca*LS* (DTSC)	**YES**	**YES**	**YES**	**YES**	**NO**

(1) Primary Receptor: Based on target human receptors at the site as defined by either current or future land use. Risk is based on most sensitive receptor at the site.

(2) Validation Studies: Refers to whether an attempt has been made to determine whether the model predicts PbB levels that are close to measured PbB levels. However, the *IEUBK* model has been shown to overpredict PbB levels.

(3) Primary Receptor: Based on target human receptors at the site as defined by either current or future land use. Risk is based on most sensitive receptor at the site.

3.3 Tiered Risk Assessment Paradigm

Residential Sites

Current risk assessment and management policy for soil lead is presented in "*Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities."* (USEPA 1994a). This policy recommends a streamlined approach for evaluating the risks associated with exposure to soil lead levels and also for setting protective levels at both CERCLA and Resource Conservation and Recovery Act (RCRA) facilities. A more recent working draft (USEPA OSWER 9285.7-50 2/12/02) titled *Superfund Lead-Contaminated Residential Sites Handbook* is being developed and will be an additional compendium of information pertaining to USEPA risk management policies. Remedial decisions are based on the results of the *IEUBK* model (for residential sites), which is applied within a tiered risk assessment approach.

The *IEUBK* model serves as both a screening tool (using default input parameters) and a site-

specific risk assessment tool in which PbB levels are more accurately predicted (if necessary) with site-specific information. There are three steps within the tiered approach (USEPA 1994b) for conducting a tiered risk assessment for lead in soil at residential sites:

- **Step 1:** Screen sites by comparing average site lead soil concentrations with the default acceptable concentration of 400 ppm for unrestricted residential use as outlined in Exhibit 9.

- **Step 2:** For sites where the average soil lead concentration exceeds 400 ppm, use the *IEUBK* model with *site-specific* data and information to more accurately predict PbB levels.

- **Step 3:** If predicted levels indicate that the PbB level is greater than 10 µg/dL in more than 5% of children then develop remediation target levels based on site-specific information.

It should be emphasized that the *IEUBK* model predicts PbB levels based on lead exposure from all environmental sources in all environmental media, including ubiquitous background lead sources. The 400 ppm screening level represents the acceptable soil concentration, which includes non-site related background lead *concentrations* in all environmental media (including food, air, and water) that are incorporated as lead intake. This is important to consider because if ambient background soil levels unknowingly exceed 400 ppm (due to lead-enriched regional soil), remediation would be unwarranted but triggered due to the lack of knowledge of background sources.

It should also be noted that some current default values used in lead models that result in the 400 ppm screening level are based on assumptions that are outdated (existed in the 1980s when the models were originally developed). For example, as previously discussed, there has been a marked decrease in environmental lead concentrations (primarily due to the ban on leaded gasoline) and the most current PbB levels should be used in the risk assessment (USEPA has not yet revised the default parameters). Incorporating the decreasing levels of lead in the ambient environment will have the effect of raising the default acceptable soil lead concentration, which is currently set at 400 ppm. USEPA further issues a cautionary note in using default parameters:

> *"For the purpose of deriving a residential screening level, the background lead exposure inputs to the IEUBK model were determined using national averages, where suitable, or typical values. Thus, the estimated screening level of 400 ppm is associated with an expected "typical" response to these exposures, and should not be taken to indicate that a certain level of risk (e.g., exactly 5% of children exceeding 10 μg/dl blood) will be observed in a specific community, e.g., in a blood lead survey. Because a child's exposure to lead involves a complex array of variables, because there is population sampling variability, and because there is variability in environmental lead measurements and background levels of lead in food and drinking water, results from the model may differ from results of blood lead screening of children in a community".*

Furthermore, USEPA emphasizes that the 400-ppm soil lead concentration is only applicable for screening sites:

> *"Screening levels are not cleanup goals. Rather, these screening levels may be used as a tool to determine which sites or portions of sites do not require further study and to encourage voluntary cleanup. Screening levels are defined, as a level of contamination above which there may be enough concern to warrant site-specific study of risks. Levels of contamination above the screening level would NOT automatically require a removal action, nor designate a site as "contaminated."*

In some situations, this explicitly stated intent has been subverted because a soil lead concentration of 400 ppm has become the *de facto* remediation goal, rather than a bright line intended to trigger subsequent investigation using site-specific exposure information.

In addition to the soil lead guidance, USEPA (1994a) clarifies distinctions and similarities between the Office of Solid Waste and Emergency Response (OSWER) Soil Lead Directive (which is applicable to CERCLA sites and RCRA sites) and Toxic Substance Control Act (TSCA) 403 Guidance, applicable to residential properties with leaded paint:

> *"Above the 400 ppm level, the Section 403 guidance identifies ranges over which various types of responses are appropriate, commensurate with the level of potential risk reduction, and cost incurred to achieve such risk reduction. For example, in the range of 400 to 5000 ppm, limited interim controls are recommended depending, as noted above,*

> *on conditions at the site, while above 5000 ppm, soil abatement is recommended. This OSWER guidance does not include comparable numbers above 400 ppm; instead, as discussed above, it recommends the site-specific use of the IEUBK model to set PRGs and MCSs, when necessary. The remedy selection process specified in the National Contingency Plan (NCP) should then be used to decide what type of action is appropriate to achieve those goals".*

More recent USEPA (1998a) Soil Lead guidance for CERCLA sites recommends:

> *"Flexibility in determining appropriate response actions that provide protection at the individual residence should be considered in context of the NCP remedy selection criteria."*

In setting 400 ppm as the soil screening concentration, USEPA assumes that it represents a soil lead level resulting in a hypothetical child or group of similarly exposed children with an estimated risk of no more than 5% exceeding the PbB level of 10 μg/dL.

Exhibits 9 and 10 present risk management stepwise decision logic for risk managers to follow.

EXHIBIT 9
RISK MANAGEMENT DECISION LOGIC FOR RESIDENTIAL SCENARIOS AT CERCLA AND RCRA SITES

STEP	ACTION
Step 1	Determine soil lead concentration at the site. If *average* soil lead concentration is less than 400 ppm, ***STOP***, no further action is required, unless special circumstances (such as the presence of wetlands, other areas of ecological risk, agricultural areas, shallow aquifers, or other areas of potentially high exposure) warrant further study. If soil lead is greater than 400 ppm, ***PROCEED*** to Step 2, unless 400 ppm is selected as a cleanup goal based on consideration of all relevant risk management factors.
Step 2	Evaluate probable land use and develop exposure scenarios.
Step 3	Collect appropriate ***SITE-SPECIFIC DATA*** based on selected scenarios. For example, sampling data may include soil and dust (at a minimum), paint, water, and air; for unique site situations, data on speciation and particle size, and behavioral activities may be required.
Step 4	Run *IEUBK* model with site-specific data to estimate risk and evaluate key exposure pathways at the site. If PbB levels data are available, compare the data to the model results.
Step 5	Where risks are significant, evaluate remedial options. If leaded exterior paint is the only major contributor to exposure, ***no Superfund action or RCRA corrective action is warranted.*** If soil is the only major contributor to elevated PbB levels, a response to soil contamination is warranted, but paint abatement is not. If both exterior leaded paint and soil are major contributors to exposure, consider remediating both sources, using alternative options. If the indoor dust levels are greater than soil levels, consider evaluating the contribution of interior lead based paint to the dust levels. If interior leaded paint is a major contributor, consider remediating indoor paint to achieve a greater overall risk reduction at a lower cost. NOTE: Available authority to remediate leaded paint under CERCLA and RCRA is extremely limited.)
Step 6	If the *IEUBK* model predicts elevated PbB levels, rerun the model using the site-specific parameters selected to reflect remedial options in Step 5 to determine site-specific PRGs or MCSs for soil.

Source: USEPA 1994a

EXHIBIT 10
RISK MANAGEMENT DECISION LOGIC FOR LEADED PAINT CERCLA AND RCRA SITES

STEP	ACTION
Step 1	Examine condition of exterior paint and determine its lead content, if any. If the paint is deteriorated, assess contribution or potential contribution of paint to elevated soil lead levels through speciation studies, structural equation modeling, or other statistical methods.
Step 2	Evaluate potential for recontamination of soil by exterior paint.
Step 3	Remediate exterior paint only in conjunction with soil.
Step 4	Examine condition of indoor paint and determine its lead content, if any. If indoor dust lead concentration is greater than outdoor soil lead concentration (because of contamination from both interior paint and outdoor soil), remediate indoor dust (e.g., through a removal action, or making HEPA-VACS available to community).
Step 5	Once the risk from indoor paint has been assessed, examine options to abate indoor paint (e.g., PRP, State, local, HUD) and consult TSCA Section 403 program for additional information and/or guidance.
Step 6	While RCRA and CERCLA have very limited authority regarding the cleanup of interior paint, the remedy may take into account the reduction of total risk that may occur if interior paint is addressed by other means. Thus, for example, a Record of Decision (ROD) or Statement of Basis (SB) may recognize that interior leaded paint is being addressed by other means, and narrow the response accordingly (possibly making this contingent on completion of the interior leaded paint abatement effort).

Source: USEPA 1994a

Non-residential Sites

At non-residential sites where children are not currently exposed or will not likely be (chronically) exposed in the future, the 400-ppm soil concentration bright line is an overly conservative screening level. Furthermore, the Adult Lead (AL) model must be used for non-residential sites because the *IEUBK* model can only be used to evaluate lead exposures in *children*. It cannot be used to establish a safe exposure lead concentration for *adults*.

USEPA (1996a) has developed an interim risk assessment guidance approach for non-residential lead exposures that is presented in *"Recommendations of the Technical Review Workgroup for Lead for an Interim Approach to Assessing Risks Associated with Adult Exposures to Lead in Soil."* The title of this document, however, is somewhat misleading since the actual target receptor is not an adult (as suggested by the title), but a hypothetical fetus that an adult woman, it is assumed, will carry to term while employed at the site. In accordance with USEPA's policy of protecting the most sensitive receptor, it has been concluded that the fetus is more sensitive to the adverse affects of lead than an adult. In other words, the Agency believes that, even for non-residential sites where children will not be directly exposed to lead in environmental media, it is plausible that a *fetus* may be exposed *in utero* via a hypothetical female worker of childbearing age. Under this scenario, the risk assessment methodology relates soil lead intake to PbB levels in women of childbearing age, which is then extrapolated to fetuses.

Similar to the tiered approach developed for residential sites, USEPA (1998a) recommends screening non-residential sites against a health-protective lead concentration for the fetus. The Agency has concluded that a reasonable screening level for soil lead at commercial/industrial (i.e., non-residential) sites is 750 ppm, but stresses:

> *"A screening goal is different from a cleanup goal. A screening goal is intended to incorporate an appropriate level of conservatism to provide for health protection in the absence of data on the specific conditions of exposure at a site. A cleanup goal can be derived using exposure assumptions based on site-specific data rather than conservative default values."*

If the site concentration is higher than the screening level, a site-specific risk assessment is warranted.

3.4 Screening Risk Assessments

3.5 Screening Levels

Screening risk assessments should be conducted to obtain a rough estimate of the magnitude of lead risks. Exhibit 11 presents a summary of acceptable soil lead concentrations that can be used to screen sites for a variety of receptors.

EXHIBIT 11
SUMMARY OF ACCEPTABLE SOIL LEAD SOIL CONCENTRATIONS BASED ON DEFAULT EXPOSURE PARAMETERS

	PRIMARY RECEPTOR			
RISK ASSESSMENT MODEL	**FETUS**	**CHILD**	**ADULT RESIDENT**	**OCCUPATIONAL**
(USEPA) IEUBK	**NA**	**400-550 ppm**	**NA**	**NA**
(USEPA REGION 8) ISE	**NA**	**1300-1500 ppm**	**NA**	**NA**
(USEPA) AL	**750-1750 ppm**	**NA**	**5750 ppm (1)**	**NA**
(DTSC) CaLS	**NA**	**94-146 ppm (2)**	**676 ppm**	**3468 ppm**

(1) The acceptable lead concentration for the *AL* model corresponds to the lowest concentration, the fetus.
(2) The range of acceptable concentrations corresponds to a child exhibiting pica and a normal child.

3.6 Conducting Screening Risk Assessments

Screening sites can be accomplished expeditiously by simply comparing the average soil concentration calculated within the exposure unit for a particular receptor and comparing this value to screening levels, which represent acceptable concentrations. If the lead concentration across the site is equal to or lower than the screening concentration, it can generally be concluded that a health threat does not exist.

Samples must be collected and evaluated to represent the average concentration. As mentioned previously, lead risk assessments differ from conventional human health risk assessments for

hazardous chemicals (conducted according to USEPA guidance), in two respects. First, unlike conventional risk assessments, in which human health risks are estimated for an individual based on assumptions for reasonable maximum exposures (RME) using upper-bound values, lead risks are based on central tendency or average values to which a geometric standard deviation (GSD) is applied. That is, instead of "trying" to determine the upper-bound estimate directly, the average PbB level is estimated and the GSD is subsequently applied to generate the entire range of plausible PbB levels around the average. It is from this distribution that the 95th percentile PbB level is derived. It is very important not to follow a conventional risk assessment approach where RME values are used to predict PbB levels because lead risks will be greatly overestimated and trigger ultraconservative and unnecessary remediation. This caveat is true even when conducting a screening lead risk assessment where default values are used exclusively. For example, with lead risk assessments, samples should not be collected in a biased manner from area(s) identified as hot spots. Furthermore, for determining the average exposure point concentration (EPC), the 95% upper confidence limit (95UCL) of the mean soil or dust concentration should not be used. Rather, the average concentration over the entire exposure unit should be determined and used as the EPC.

3.7 Site-Specific Risk Assessments

The common element for all lead risk assessments is that they are all based on mathematical representations of physiological processes. In other words, they take the amount of lead in environmental media, such as soil, and convert it into serum PbB levels using behavioral assumptions and pharmacokinetic processes. Prior to discussing the individual risk assessment models, the following brief sections present guidance for conducting sampling and analysis, which is applicable for all lead risk assessments. This is a pivotal step for all risks assessments because, once samples are collected, they will be used to establish exposure point concentrations that will directly influence predicted PbB levels. Incorrect or biased sampling can result in overestimating risk. Therefore, samples collected for purposes other than representation of the average lead exposure may lead to flawed results. For example, samples collected to define the nature and extent of contamination may not be appropriate for risk assessment purposes.

3.8 Developing a Sampling Plan

The first step in developing a sampling plan is identifying what environmental media need to be

sampled. Part of this process is to first identify the predominant exposure pathways for the site. For example, soil ingestion is commonly a predominant pathway for small children, and planning to take soil samples requires developing a detailed conceptual site model to determine how and where exposure to soil will occur (another obvious reason soil samples *must* be collected is that, unlike other environmental media where default values exist, there are no default values for soil). Sampling should also be conducted when there is reason to believe that site-specific levels differ from default values or the assumed relationship between different environmental media is not consistent with site-specific conditions. For example, the amount of lead-containing dust is, by default, assumed to be a dependent on the concentration of outdoor soil lead. However, indoor dust may be higher or lower than outdoor soil depending on a number of environmental and behavioral factors.

3.8.1 What Environmental Media Should be Sampled?

All lead risk assessment models are multi-media models that predict PbB levels from a comprehensive list of lead sources. Sources of lead include past and present lead releases at the site, as well as those related to natural or ambient background sources (unrelated to site activities). Plans must be developed to distinguish between site-related and non-site related sources. Although it is preferable to collect samples from all environmental media, it may not be cost effective or fit within the time frame of the project. Therefore, a focused sampling program must take many factors into account in a cost-benefit analysis before sample collection begins. Fortunately, it is not absolutely necessary to sample all environmental media because default values, based on national or regional statistics, are available. Exhibit 12 presents a summary of data requirements for each of the 4 lead risk assessment models for each environmental medium where either default lead levels are assumed or site-specific lead levels must be quantified.

EXHIBIT 12
DATA REQUIREMENTS FOR LEAD RISK ASSESSMENT MODELS

	DATA REQUIREMENTS				
RISK ASSESSMENT MODEL	**AIR**	**DRINKING WATER**	**SOIL**	**DUST**	**FOOD**
IEUBK	**SS/DFT**	**SS/DFT**	**SS**	**SS/DFT**	**SS/DFT**
ISE	**SS/DFT**	**SS/DFT**	**SS**	**SS/DFT**	**SS/DFT**
Adult Lead Model (AL)	**NA**	**NA**	**SS**	**SS/DFT**	**NA**
CaLS Model	**SS/DFT**	**SS/DFT**	**SS**	**SS/DFT**	**SS/DFT**

SS/DFT Site-specific data is preferred, but default values, based on national averages, are available in the absence of site data.

SS: Site-specific data is necessary.

NA: Not applicable because model does not directly evaluate environmental media. Instead, national background PbB levels are already accounted for.

3.8.2 Where Should Samples Be Collected?

Environmental media that should be sampled depend on the risk assessment model used (*IEUBK*, *AL*, *CaLS*, or *ISE* models), the required accuracy and precision of the risk estimate, and potentially impacted environmental media. The *IEUBK* model, which is a multimedia model, requires lead concentrations as input parameters for multiple sources of lead (i.e., food, water, soil, dust, and air). In contrast, the *AL* model requires that samples only be collected for soil and dust lead.

Samples should be collected in manner that will represent the average exposure to lead over an extended period of time (e.g., for children, the duration is approximately 6 years). However, this will require a detailed site conceptual model that incorporates not only how the concentration of lead is distributed in the environment, but also the amount of time a receptor spends in contact with different areas. Additionally, activity patterns within the exposure unit may change over the years as the child matures.

The areas in which exposures occur are considered exposure units and represent the areas where the receptors spend most of their time. The most important aspect to consider in choosing sampling locations within the exposure unit for a particular receptor is whether exposure will be random or biased. Typically, in conducting lead risk assessments for existing residential properties, sufficient information can be gathered during a site visit to identify areas most frequented by the receptors, as well as the percentage of time spent in those areas. This information cannot only be used to determine areas to be sampled, but can be used to derive an estimated weighted average that accurately reflects the average lead exposure anticipated during the day. However, for most sites, random sampling most closely parallels random exposure as indicated by USEPA Region 8 guidance (1996b), which states:

> *"Based on this, in the general case, the sample locations should not be biased toward over-representation of areas that are expected to contain higher-than-average lead levels (e.g., drip lines), areas where exposure is suspected to occur more frequently than other areas (e.g., a play area) or areas where contact with soil is thought to be more likely than for other locations (e.g., a bare area). The reason that biased sampling is not appropriate is that there is no method by which such biased data can be used to derive an unbiased estimate of the true mean over the exposure area (USEPA 1994). Rather, the exposure unit should be sampled using a systematic sampling pattern to ensure balanced representation of all areas of the unit."*

In contrast, in sample locations for undeveloped sites (perhaps involving property transfers) where exposure units can not yet be defined, all samples should be collected randomly within an area that can reasonably anticipated to represent an exposure unit in the future. The first step in this process involves determining what type of population will be exposed to the property (e.g., occupational or residential). The second step is to obtain local building codes or master plans for the region to determine the size of the exposure unit for the particular type of receptor. For example, if residential development is the most likely anticipated future development, and local building codes require a minimum of one-half acre plots of land for each residential site, the property to be transferred should be divided into similar units and random samples should be collected within each one-half acre parcel.

3.8.3 When Should Samples be Collected?

Lead is relatively stable in most environmental media, so there is little seasonal variability with the possible exception of water and indoor dust. For CERCLA sites, USEPA is not interested in ground water. For indoor dust, the lead levels can change seasonally due to such weather-related aspects such as the windows being open or shut, mud tracked in, areas covered with snow, etc. Care should be taken to ensure indoor dust samples truly represent the yearly long-term average and not just a period where indoor dust is expected to be extraordinarily high or low.

3.8.4 How Many Samples Should be Collected?

Site-specific conditions and risk management criteria should guide sampling. In general, fewer samples will need to be collected from sites where lead concentrations are fairly homogeneous, as opposed to heterogeneous sites where more samples will be required to estimate the exposure concentration. Thus, the three factors most important in determining how many samples should be collected (USEPA 1996b) are as follows:

- Desired accuracy;
- Sample variability; and
- Estimated average concentration.

With unlimited resources and time with which to evaluate a possible lead-contaminated site, multiple samples could be collected and analyzed for lead in every environmental medium at every plausible location to predict PbB levels. However, this approach is impractical for most sites. Issues such as cost and schedule will be the predominant factors in developing a sampling strategy. How many samples, and whether or not any "special" site-specific analyses or investigations are required to estimate PbB levels will be based on professional judgment.

The data collected to determine the nature and extent of contamination should be used cautiously. Biased sampling, where the sole intent is to identify "hot spots," should not be used in the risk assessment. That is, it is not appropriate to select the boundaries of exposure based on the nature and extent of environmental patterns of soil contamination.

Soil

The appropriate number of samples in the correct locations to represent plausible long-term

average exposure for lead in soil is critical for accurately predicting PbB levels and lead risks. Furthermore, it is important to implement a sampling and analysis strategy that can be used to differentiate background and site-specific sources of lead. For remediation purposes, site-specific sources of lead should be the primary focus of the risk assessment and not ubiquitous or ambient background lead. Not all lead resulting from off-site anthropogenic activities should be classified as site-specific hazardous waste releases. Lead will always be present and detected in all environmental samples collected at any location in the United States. Therefore, the total number of samples collected should include a representative number of background samples.

Lead in soil should be the central focus of any lead risk assessment because lead intake is (typically) greatest from this medium. It is the single most important environmental medium for two reasons. First, there are no default values that can be used as proxy values for soil lead as it is the most likely medium to be clearly related to site-specific lead releases. Second, input parameters for other environmental media are dependent on soil lead concentrations. For example, lacking indoor lead dust data, it is assumed that dust concentrations will be present in proportion to the outside soil lead concentration.

When the assumption of random exposure over the exposure unit is not considered to be realistic, then the exposure unit may be divided into sub-areas. Random samples should be collected within each of the sub-areas and the sub-areas subsequently combined to develop an exposure point concentration. The objective of this approach is to develop a soil lead data set that will accurately predict PbB levels in *current* residents.

The number of samples necessary to make accurate PbB level predictions depends on site-specific conditions. When soil lead concentrations represent a small fraction or a very large portion of the overall lead risk, then high accuracy is not needed to make risk management decisions. That is, high accuracy is not needed for sites where the predicted PbB level is well above or below 10 μg/dL. Only sites where predicted PbB levels are close to 10 μg/dL will require sufficient samples to accurately and confidently make the correct risk management decision.

In general, more samples will be required for sites that require high accuracy and have high intrinsic variability. Exhibit 13 presents the 95% confidence limits about the mean as a function of sample number and variability, as represented by the GSD (USEPA 1996b). As shown, UCL/mean and LCL (lower confidence limit)/mean ratios asymptotically approach 1.0, which

represents a point at which no uncertainty in the data set exists. It is important to note that uncertainty in the estimate of the mean concentration decreases with more samples, regardless of the GSD, and uncertainty is higher for data sets with high variability (GSD) than lower variability. From a practical standpoint, it is also important to note that, after a certain point, taking more samples does not appreciably reduce uncertainty. It is not cost effective to attempt to reduce the uncertainty by more than a factor of 1.2 to 1.3 by collecting more samples (flat part of the curve in Exhibit 13). It is imperative to collect enough samples to accurately estimate exposure point concentrations in all lead risk assessments because the effect of the calculated P10 is very sensitive to small changes in the average soil concentration. (The probability that the PbB level of 10 μg/dL will be exceeded is often referred to as the "P10.") Exhibit 13 shows the sensitivity of the average soil lead concentration as a factor of variability (or range of concentrations).

EXHIBIT 13
UNCERTAINTY IN EXPOSURE POINT CONCENTRATION DECREASES AS THE NUMBER OF SAMPLES INCREASES

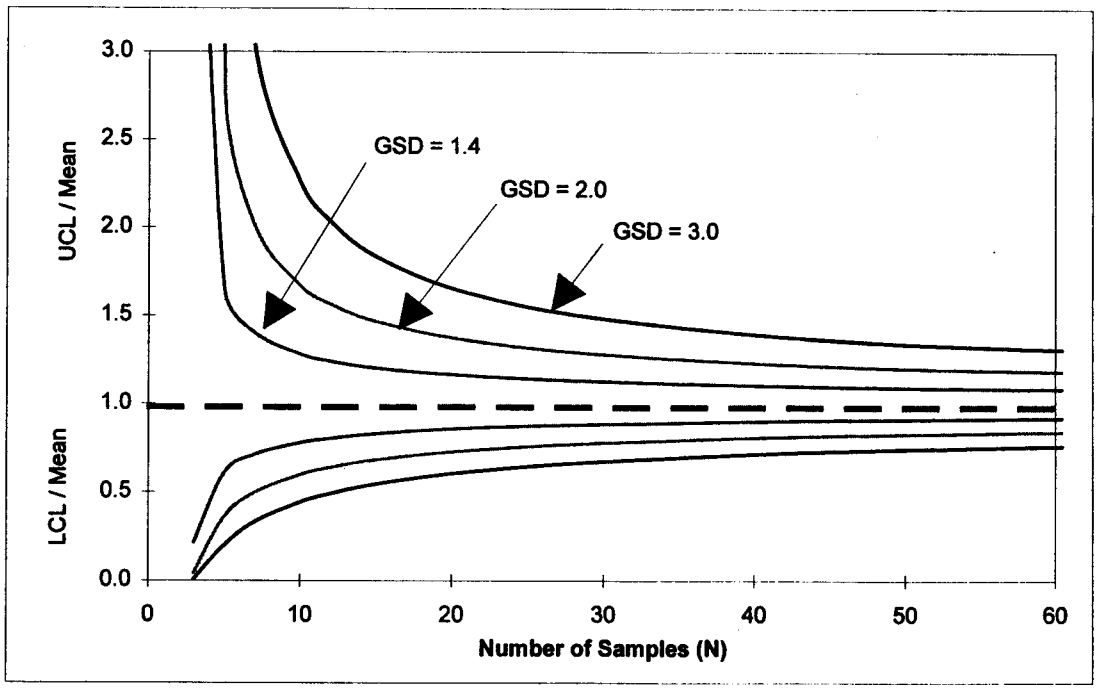


Exhibit adapted from USEPA (1994b)
UCL – Upper confidence limit on the mean concentration.
LCL – Lower confidence limit on the mean concentration.
GSD- Geometric Standard Deviation
Note: A value of 1.0 represents the point at which both the UCLs equal the mean concentration.

Confidence intervals around the value of P10 are much larger than the confidence intervals around the value of the mean soil concentration. This range can span the decision threshold (P10<5%) when soil concentrations are between 300 and 600 ppm, which is close to the *default* decision threshold for risk management decision (site-specific conditions may increase the acceptable lead soil concentrations). In this range of soil lead concentrations, it is very important to collect sufficient samples to accurately estimate the PbB level.

Exhibit 14 shows the number of samples required to estimate the average lead concentration within a factor of 1.3 to 2.0 for sites having low, medium, and high variability. For example the number of samples required at a relatively heterogeneous site (where the data variability is high; GSD = 3.0) will be 60 and 12 samples when it is required that the average concentration be

estimated within a factor of 1.3 and 2.0, respectively. It is not practical to define the mean concentration more accurately than within a factor of about 1.2 to 1.3. When insufficient data are available to make an *a priori* determination about the variability of the sites, USEPA Region 8 (1996b) recommends using a default GSD of approximately 2.0. This would require approximately 30 samples from each exposure unit, but costs may be reduced by compositing samples across the exposure area. Compositing samples is appropriate because the calculated mean concentration of *n* samples is expected to approximate the single measured value for a composite of those same *n* samples.

EXHIBIT 14
NUMBER OF SAMPLES REQUIRED TO ESTIMATE MEAN SOIL LEAD CONCENTRATION

	NUMBER OF SAMPLES REQUIRED		
Variability	**Estimating The Mean Within A Factor Of 1.3**	**Estimating The Mean Within A Factor Of 1.5**	**Estimating The Mean Within A Factor Of 2.0**
Low Variability (GSD=1.5)	**10**	**7**	**5**
Medium Variability (GSD=2.0)	**30**	**15**	**7**
High Variability (GSD=3.0)	**60**	**30**	**12**

There are three important sources of variability:

- Spatial Variability;
- Temporal Variability; and
- Analytical Variability.

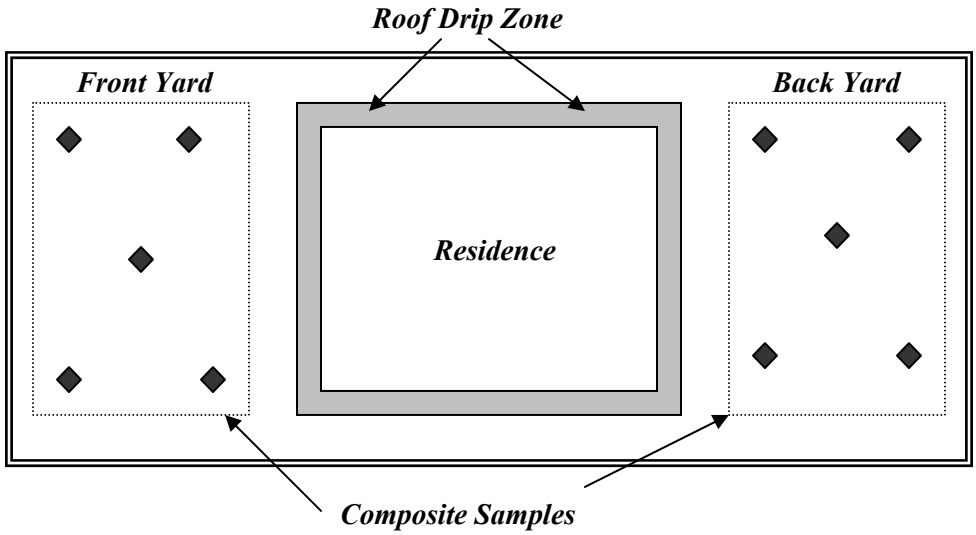
Of the three sources of variability, spatial variability is likely the greatest. This represents the differences in concentration within each exposure unit within a two-dimensional framework. It should be stressed that spatial variability typically refers only to a two-dimensional framework within soils because—at least in the case of modeling lead exposure to children—subsurface soil is usually an incomplete pathway. That is, depth of soil sampling should represent that portion of soil where exposure is expected to occur. Although there is no regulatory standard or formal definition for surface soil, soil collected at depths from 0.5 to 2 inches below ground surface is typically used to represent residential exposure (USEPA 1996b).

The number of samples collected from each exposure unit depends on the sampling and analysis strategy planned for the site. Two sampling strategies should be considered for collecting multiple soil samples within a residential exposure unit. In the first strategy, discrete samples are

collected and analyzed individually. This approach should be followed when hot spots are thought to exist within the exposure area (however, hot spot data should only be used to estimate PbB levels when it is located within the exposure area and a weighted average used to represent the fraction of time spent in the hot spot). Additionally, discrete sampling can reveal information on soil variability across the exposure area. However, the cost for discrete sampling and analysis can be high and yield little useable information when lead concentrations are relatively homogeneous. Before implementing a discrete sampling and analysis approach, the site conceptual model should be developed together with a cost-benefit analysis to determine whether additional costs are warranted.

The second sampling strategy involves combining or compositing individual soil samples into a single sample that is subsequently analyzed. For most sites, this approach will significantly reduce sampling and analysis costs with no loss of site information. The single composite sample concentration can be used directly in the lead risk assessment to represent a best estimate of the average exposure point concentration across the exposure unit because it is analogous to averaging individual discrete samples. The only disadvantage of the composite sampling approach is that it may not reveal the presence of hot spots. However, the primary goal of any sampling program for lead risk assessments is to determine the average lead concentration, not the highest or 95% UCL concentration. Additionally, for fairly homogeneous sites having only one source of lead, compositing samples is preferred. Exhibit 15 shows an example of sampling locations that could be collected for a composite sample. Lead-contaminated soils are frequently found within the drip zone of houses resulting from fine airborne particulate matter deposited on the roof and subsequently transported to the areas around the house foundation. Rooftops may collect fine-grained soil particles that contain lead. The source of this material may either be ambient background or site-specific. In yard areas where downspouts discharge during a storm event, it may cause a localized increase in soil lead concentrations which could be considered a hot spot. However, samples collected from this area should only be used in the risk assessment if the site conceptual model has identified the drip zone as a potential play area for children, and if so, the data from this area should be weighted based on the amount of time children spend in the area.

EXHIBIT 15
EXAMPLE SAMPLING LOCATIONS FOR COMPOSITED SOIL SAMPLES TO ESTIMATE THE AVERAGE EXPOSURE POINT CONCENTRATION FOR A RESIDENCE



When composited sampling is conducted, the results of the risk assessment should not be used to automatically force an "all or none" remedial decision at a particular residence. Subsequent discrete sampling should always be conducted to determine whether remediation of the entire site or only a small portion is necessary. This two-step sampling approach can save on sampling costs.

The number of samples combined in a composite sample should be at least three and no more than 10 (USEPA 1996b). Samples should always be composited to represent discreet portions of the exposure unit and not be composited randomly. Compositing in this manner will allow small areas within each exposure unit to be identified if subsequent remediation is warranted. Other sampling strategies intermediate between discreet and compositing sampling should be considered if they yield the necessary data for risk assessments. For non-residential sites, samples must also be collected in a manner that will yield the *average* exposure point concentration for long-term exposures. USEPA (1996b) defines the EPC as "the portion of soil to which adults are most likely exposed." Exposures are also assumed to occur on a regular or daily basis randomly across the exposure area over the year(s). Under both current and future exposure

scenarios, an arithmetic mean concentration should be estimated based on the specific exposure area that a worker would plausibly be expected to contact on a regular basis. It is important to collect data from all areas that are known to be affected, as well as areas where lead releases have not occurred, since the average exposure is assumed to be random across the entire site. USEPA suggests using half an acre as a reasonable default exposure area for outdoor workers; however, site-specific information or conditions may suggest that workers are exposed to a greater area (e.g., lineman) or a smaller area (e.g., small commercial facility site).

As with residential sites, background conditions should be evaluated with non-residential sites to develop a practical, cost-effective remediation strategy. Recent geochemical analytical methods have been developed to provide not only site-specific background information, but also background information on a sample-by-sample basis.

Indoor Dust

After soil, indoor house dust is the next-most important environmental medium requiring that site-specific data be collected. However, determining dust lead concentrations is not an absolute requirement, and samples do not necessarily have to be collected. Unlike soil lead data, for which there are no default options, there is a conservative default approach for estimating indoor dust lead concentrations.

Site-specific dust lead concentrations should be determined when exposure to indoor dust lead is expected to be significant. However, dust measurements may not be possible under some circumstances, and a default approach must be used. The default assumption (USEPA 1994b) is that 70% of indoor dust lead is contributed by outdoor soil lead. This relationship is expressed as:

$$\mathbf{C}_{dust} = \mathbf{0.70} * \mathbf{C}_{soil}$$

This default proportionality is based on empirical data collected at a number of *residences* and may be an appropriate value for many risk assessments. At other sites, the contribution of soil lead is substantially lower than the 70% default, in which case, PbB levels could be overestimated. A major factor contributing to residential dust lead levels is the normal behavior of children and pets, which physically transport soil lead particles into houses. Consequently, this default relationship should only be used at residential sites.

For non-residential sites, the default dust value of 70% will likely overestimate the "true" site-

specific indoor dust lead concentrations for occupational exposures. This could result in exceeding some health-based target for indoor workers or triggering unnecessary remediation. The primary reason is that children and family pets (responsible for transporting soil lead into homes) are not present at office buildings. The contribution of resuspended soil lead to dust lead will be even lower in office buildings that are climate controlled (where windows are shut) and/or the site has landscaped ground cover. Consequently, residential default values for dust lead should not be used (unless there is no practical alternative) to evaluate non-residential exposures. In the long term, it will usually be cost-effective to collect indoor dust lead samples because dust samples may be the only data requirement to estimate non-residential PbB levels (assuming there is no direct contact with outdoor soil). If soil concentrations are used to calculate dust concentrations, risks will be overestimated at many non-residential sites.

Interior and Exterior Paint

Interior or exterior leaded paint can be an important source of lead exposure that can occur directly (ingesting paint chips) or indirectly (ingesting soil contaminated by lead chips). Measuring the fraction of lead in paint may, therefore, be important. Evaluating the condition of the paint is equally important in order to determine if the paint is tight, weathered, chipping, peeling, or flaking.

Although leaded paint data may be useful for making risk management decisions, samples should not be taken for estimating PbB levels in lead risk assessments for several reasons. First, no risk assessment model can directly evaluate paint chip ingestion. Direct ingestion of paint chips is expected to be intermittent and not chronic (USEPA 1996b), resulting in temporary "spikes" in PbB levels that cannot be quantified with current risk assessment paradigms. Although direct paint ingestion may be an acute hazard, few studies have measured the toxic effects from lead paint chip ingestion, and it is not currently possible to include this particular type of exposure in risk assessments. For example, while it is presumed that ingesting an occasional paint chip will cause a relatively large increase in PbB levels, it is not known how long the PbB levels remain high or what the corresponding toxic effect will be.

Second, when soil and dust lead levels are measured and used in the risk assessment to predict PbB levels, the contribution of leaded paint to overall exposure is *already* accounted for. Thus, there is no need to measure lead levels in paint, at least for risk assessment purposes. The only reason to sample for leaded paint and determine the condition of the painted surface is to

determine if it is currently an important source of lead loading to other environmental media or will likely become an important source in the future. Risk management decisions may be influenced by such site-specific information regarding lead sources.

Drinking Water

Based on the volume of water ingested each day and the bioavailability of soluble forms of lead, lead in drinking water can contribute significantly to PbB levels. However, as noted earlier samples are not necessary for sites where a municipal water supply exists. Where it may be appropriate is when a lead release at the site has entered a private well, which is rare. Assuming that the main purpose of the risk assessment is to focus on risks from lead released to the environment from a site-related activity, in most circumstances it will only be necessary to analyze lead levels in source water. When the water for the site under investigation is a municipal supplied water source, it is conventional to assume the municipality is in compliance with regulatory drinking water standards (maximum contaminant levels; MCLs) unless unusual site-specific conditions exist.

Airborne Lead

The physical properties of lead limit the amount and physical form of lead that can be inhaled. Lead does not exist in vapor form and, in most cases, is adsorbed to small dust particles, which can reach the lung only if they are sufficiently small. It is generally assumed that lead-bound particles must be smaller than 10 microns (μm) in diameter to enter the lungs. However, the inhalation pathway is relatively insignificant compared with soil, dust, and food ingestion, so it may not be cost-effective to spend time or money collecting airborne lead data. Using the default exposure assumptions in the *IEUBK* model for a child aged 2 to 3 years and the default assumption regarding the amount of soil that exists as respirable particles in air, the ratio of the lead dose from inhalation of PM_{10} (particulate matter that is 10μm in diameter) to the dose from ingestion of soil and dust is as follows (USEPA 1996b):

$$DIair/\ DI_{soil} = (C_{air} * BR)/\ (C_{soil}\ (IRs + 0.7IR_d))$$

Where:

DI_{air}	=	Daily intake of lead from air (μg/day);
DI_{soil}	=	Daily intake of lead from soil and dust (μg/day);
C_{air}	=	Concentration of lead in air (μg/day), estimated as $C_{air} = C_{soil}$ * **PEF** (particle emission factor; 2E-4 mg/m^3);
BR	=	Breathing rate (5 m^3/day)
IR_s	=	Ingestion rate for soil (61 mg/day); and
IR_d	=	Ingestion rate for dust (74 mg/day).

Using these default values, the inhaled dose of lead from soil suspended in air is less than 0.001% of the daily-ingested dose of soil and dust lead. Therefore, there is generally no need to collect site-specific air lead data for risk assessment purposes. Instead, regional yearly average airborne concentrations should be used to estimate risk.

The USEPA Office of Air Quality Planning and Standards (OAQPS) has set National Ambient Air Quality Standards for lead, which is one of the "criteria" pollutants. The primary and secondary standard for lead is 1.5 μg/m^3, based on a quarterly average. As a priority pollutant, ambient air levels of lead are continuously measured at all monitoring stations throughout the United States. The ambient concentration for most sites can be found in the AIRS*Data* database (http://www.epa.gov/air/data/index.html). It provides annual summaries of lead concentrations measured at individual monitoring stations and identifies the locations of monitoring stations.

3.8.5 Should Demographic Data Be Collected?

For those Navy Installations where existing residential sites are under investigation, it may be possible to conduct surveys to gain additional information regarding exposures that would improve the accuracy of the lead model PbB level predictions. For example, information on time spent at the residence, and fraction of time spent indoors and outdoors could be useful. Also, behavioral activities such as hand-to-mouth activity in children can be directly observed while at play. While this information may or may not be helpful in estimating lead risks, it may serve to address some uncertainty, which is inherent in all risk assessments.

3.8.6 Should Blood Samples Be Collected?

All lead risk assessment models are predictive, and the predictions are only as accurate as the data, information, and assumptions used in the risk assessment. The only way to verify accuracy is to directly measure PbB levels in the exposed populations. However, the costs and effort of conducting blood test can be prohibitive and prolonged.

If blood samples are collected, a sufficient number of children (or other exposed populations) must be included in the study, and they must be representative of the exposed population. Additionally, any seasonal variation in exposure levels and concomitant PbB levels must be factored in the study design.

Because lead risk assessments are frequently criticized for not being sufficiently health protective or ultraconservative, measuring PbB levels in blood of exposed individuals offers an opportunity to directly test the validity of the risk assessment and can, therefore, be a valuable risk management tool.

3.8.7 Should Lead Bioavailability Studies Be Performed?

Lead bioavailability is a major influence on the uptake of lead from the gastrointestinal tract to the blood stream. Therefore, bioavailability studies should be conducted if at all possible.

Lead exists in the environment in many different chemical and physical states. It is important to determine the site-specific form of lead in order to make accurate PbB level predictions. This information is necessary, regardless of the lead model used or the type of receptor at the site. It is a key piece of information in predicting PbB levels because lead with low bioavailability will result in a correspondingly lower PbB level compared with the same dose of lead with high bioavailability. Lead that is ingested, but not absorbed, passes harmlessly through the body (eliminated in the feces). Unlike risk assessments for other chemicals where the total amount of chemical "ingested" is simply calculated and used to predict human health risks (often without consideration of the amount of chemical that is actually "bioavailable"), lead risk assessments require that the fraction of lead actually absorbed into the body be determined or a default assumption used.

Specific terminology referring to the "availability" and "absorption" of lead into the body has been defined by USEPA (1994b). It is important to note that lead in soil must first be dissolved and in a soluble state before any absorption into the bloodstream can occur. This means that lead bioavailability must be evaluated as a two-step process:

- **Step 1:** Determine the fraction of lead (i.e., soil and dust lead) that is soluble or can be made soluble in the gastrointestinal tract.

- **Step 2:** Determine how much of the soluble fraction can be absorbed into the blood.

The term "bioaccessability" is frequently used to describe the fraction of ingested lead that becomes solubilized in the gastric fluid. However, bioaccessability is related to bioavailability, not simply as the total amount that is soluble, but also the *rate* at which lead becomes soluble.

Though the general term "bioavailability" refers to *"the fraction of the total amount of material in contact with a body portal-of-entry such as the lung, gut, and skin that enters the blood"* (USEPA 1994b), there are different types of bioavailability. Bioavailability is also described as absolute or relative. Absolute bioavailability is the amount of lead entering the circulatory system (blood) following ingestion, divided by the total amount administered. For practical reasons, absolute bioavailability is typically calculated as the percent of fractional uptake of lead following ingestion of an injected dose, where the injected dose represents 100% absorption. In contrast, *relative* bioavailability represents the fractional bioavailability of a particular form of lead relative to the bioavailability of a soluble form of lead, such as lead acetate.

Studies have demonstrated that there is great variability in bioavailability associated with different soil and dust matrices (Casteel *et al*. 1997; Henningsen *et al.* 1998; Steele *et al.* 1990). They have identified the following three-physical/chemical aspects that strongly influence bioavalability and which must be considered in lead risk assessments:

- Soil and dust particle size;
- Mineralogical or chemical form; and
- Lead speciation and physical matrix (extent to which lead is encased in inert mineral material).

Exhibit 16 presents a summary of the relative bioavailability of different forms of lead, as determined by Henningson *et al.* (1998). As indicated, the relative bioavailability of different mineral lead forms can vary considerably. USEPA Region 8 has conducted *in vivo* animal experiments that show a general pattern of relative bioavailability for certain lead salts. Lead speciation has been identified as a key factor influencing bioavailability. This archival information can be used to compare bioavailability based on the site-specific lead minerological form to that used as the default value. If the lead form is significantly different from the form that the default value is based on, then the site-specific form should be used instead of the default value (assuming supporting information is available or can be gathered).

EXHIBIT 16
RELATIVE BIOAVAILABILITY OF DIFFERENT MINERAL FORMS OF LEAD

	RELATIVE BIOAVAILABILITY		
	Low (Less Than 25%)	**Medium (Between 25 and 75%)**	**High (More Than 75%)**
Mineral Form Of Lead	**Galena (PbS)**	**Pb Oxide**	**Cerrusite (PbCO3)**
	Anglesite (PbSO4)	**Pb Fe (metal) Oxides**	**Pb Mn (metal) Oxides**
	Pb (metal) Oxides	**Pb Phosphate Slags**	
	Pb Fe (metal) Sulfates		
	Native Pb		

Source: Adapted from Henningsen *et al*. (1998)

Geochemical analysis also provides information about different lead sources at a site. For example, lead speciation data can be used to differentiate the fraction of soil and dust lead attributable to paint chips or flakes, naturally occurring background, and anthropogenic background conditions. USEPA Region 8 suggests that at least a limited soil characterization study be conducted for lead risk assessments. Although some sites may require detailed analyses, it may be possible to identify paint chips or flakes with a light microscope. This circumvents costly analysis with electron microscopic or microprobe analysis.

The rate and amount of soluble lead absorbed in the gastrointestinal tract is dependent on the following two components:

- Passive absorption; and
- Facilitated or active absorption.

- Guide for Incorporating Bioavailability Adjustments into Human Health and Ecological Risk Assessments at U.S. Navy and Marine Corps Facilities, Part 1 - Final July 2000 (79 pages)

- Guide for Incorporating Bioavailability Adjustments into Human Health and Ecological Risk Assessments at U.S. Navy and Marine Corps Facilities, Part 2 - Final July 2000 (159 pages)

These files are located on NFESC's web server at http://enviro.nfesc.navy.mil/erb EXIT→W3 under *Navy Support* > *Work Groups* > *Bioavailability*.

The *passive* component refers to the type of absorption that does not depend on lead concentration in the gastrointestinal tract and is not saturable. In other words, there is no limit to the amount of lead that can be passively absorbed. The *facilitated or active* component may become saturated and rate limiting when the total concentration of lead in the gut is sufficiently large. The importance of these components in the risk assessment is that there is a finite amount of lead that can be absorbed by the body at one time. Absorption will not always be proportional to the amount of lead ingested or the amount of lead solubilized in gastric fluid.

As Exhibit 17 shows, as the mass of soil ingested increases, the relative bioavailability decreases.

EXHIBIT 17
RELATIVE BIOVAILABILITY IS DEPENDENT ON THE AMOUNT OF LEAD INGESTED – IT DECREASES WITH INCREASED INGESTION

PbB Levels For Calculating Relative Bioavailibility (μg/dL)	Dose Of Soluble Lead To Achieve PbB Level (mg/kg/day)	Dose Of Soil Lead To Achieve PbB Level (mg/kg/day)	Relative Bioavailability
1.0	0.03	0.04	0.78
2.0	0.07	0.10	0.71
3.0	0.11	0.17	0.65
4.0	0.15	0.27	0.58
5.0	0.20	0.40	0.50
6.0	0.25	0.60	0.42
7.0	0.30	0.93	0.33
8.0	0.36	1.60	0.23

The current USEPA position is that *in vivo* animal bioassays using actual site soil or dust constitute the only way to confirm site-specific bioavailability. For large sites where the anticipated remediation costs are expected to be high, conducting bioavailability studies may be a cost-effective risk management step.

USEPA Region 8 (1996b) suggests the following three possible approaches for investigating site-specific bioavailability:

- Measure the bioavailability of lead in an appropriate *in vivo* animal study;
- Measure the solubility of lead in an *in vitro* test system, and estimate the bioavailability by extrapolation; and
- Characterize the physical and chemical forms of lead present by light or electron microscopy.

The first option is the most direct and scientifically tenable approach. However, this type of animal experiments may be costly and complex in design and interpretation. This option should only be considered after conducting a cost-benefit analysis in which the cost of remediation is weighed against the cost of the animal study.

The second option is an *in vitro* ("test tube") study. Some fast and cost-effective *in vitro* tests have been developed, but they have not yet been verified. Moreover, *in vitro* assays do not directly measure bioavailability. They only provide information on potential bioaccessibility (or solubility). The results can be influenced by slight changes in pH, time, temperature, volume, other solutes, and agitation. However, if an *in vitro* test indicates that soil or dust has very low solubility, this can be used as supporting information.

The third option involves electron microscopic analysis. USEPA (1996b) has conducted lead bioavailability measurements on a number of different soils from contaminated sites across the country. These soils were geochemically analyzed with electron microprobe analysis, so it may be appropriate to extrapolate results to other soils with similar geochemical composition. It will only be possible to extrapolate after the geochemical composition of the reference test material is confirmed to be similar.

According to USEPA (1996b), soil and dust samples that are tested for *in vivo* bioavailability or *in vitro* bioaccessibility should be representative. The top 2 inches of surface soil from residential yards should be composited for testing and sieved to less than 250 μm to closely represent the size of soil particles that would be expected to adhere to children's hands.

Finally, the importance of determining bioavailability is illustrated in Exhibit 18, where the percentage bioavailability dramatically alters the PbB level and the calculated target remediation level.

EXHIBIT 18

EXAMPLE OF THE SENSITIVITY OF SOIL LEAD BIOAVAILABILITY ON PREDICTED PBB LEVELS

SITE-SPECIFIC CONDITION	P10 LEVEL	SOIL LEAD BIOAVAILABILITY	CLEANUP LEVEL BASED ON SOIL LEAD BIOAVAILIBILITY
One-half Default Bioavailability	0.11 %	15 %	1075 ppm
Default Bioavailability	5.0 %	30 %	530 ppm
Doubling Default Bioavailability	43.14 %	60 %	265 ppm

3.8.8 Should Background Analyses Be Conducted?

Delineating the zone of site-specific contamination requires distinguishing soil with "background" lead concentrations from soil that has been impacted by site-related activities. It is also important to recognize that each sample collected at Navy Installations is composed of a background source (which is not related to site activities) and a site-related release. At some sites, the fraction of background lead in each sample may be significant. If a background analysis is not conducted, the percentage of the estimated PbB level predicted with lead models may be unknowingly associated with background conditions. Therefore, background analyses should always be conducted as part of a lead risk assessment to distinguish the fraction of PbB level resulting from background and site-specific lead concentrations.

USEPA (1995b) emphasizes the need to conduct background analyses and strongly cautions against automatically interpreting high concentrations of lead as site-related:

> *"Almost anyone involved with hazardous waste site evaluations will at some time be involved in determining background concentrations of inorganics at a site. There are two issues to be considered when addressing background. The first is whether the site and local area have a high natural variability in concentrations of inorganics. The second is to differentiate between natural and anthropogenic sources at a site with high*

> *background concentrations (e.g., lead in soil due to automobile emissions). The broad range in concentrations of naturally occurring inorganics may lead to the erroneous conclusion that an area has been contaminated with inorganics."*

High chemical concentrations are part of natural variability and are expected. A chemical release of lead is indicated only when a high *number* of samples exceeds some expected number *and* the sample locations are clustered within a small area (i.e., they are co-localized).

Anthropogenic Background Lead Levels

According to USEPA (1995b), anthropogenic background lead conditions are defined as those resulting from human activities, but which are unrelated to site operations. Anthropogenic background conditions can result from (1) historical operations that occurred prior to site development, or (2) chemical releases from off-site or regional sources. Anthropogenic background lead levels are usually the result of deposition of airborne lead in the air from stationary (stack emissions) and non-stationary sources (vehicular exhaust). Sampling and analysis plans should be developed to identify anthropogenic non-site related sources of lead at all sites, regardless of the region in which the site is located, because anthropogenic background conditions exist in both urban and rural areas.

Urban Areas

Although lead-containing paint may initially be identified as the primary source of lead at urban sites, this conclusion should only be based on the results of careful sampling and chemical analysis. At many sites, soil lead may simply be due to deposited vehicular exhaust from local traffic. Samples collected near garages, parking areas, or driveways are frequently high in lead resulting from historical deposition of automobile exhaust. Exhibit 19 presents soil lead concentrations developed by USEPA showing the elevated anthropogenic lead levels that have been detected in a variety of urban soils.

EXHIBIT 19
ANTHROPOGENIC BACKGROUND CONCENTRATIONS OF SOIL LEAD

Site And Anthropogenic Source	Concentration Range (mg/kg)
Urban Garden And Urban Vicinity	**218-10,900**
Roadside Soil	**960-7,000**
Lead Metal Processing Industry	**500–6,500**
Non-Ferric Metal Mining	**15–13,000**

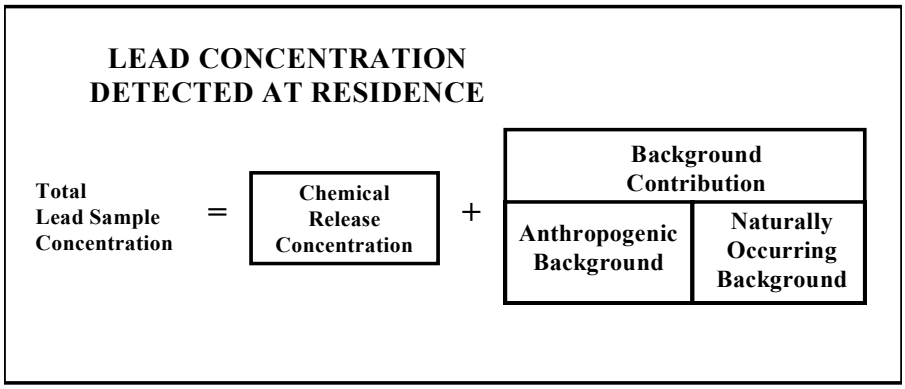
Source: *Determination Of Background Concentrations Of Inorganics In Soils And Sediments At Hazardous Waste Sites* (USEPA 1995b).

It is well documented that soils next to high-density or high-traffic roadways have very high concentrations of lead as a result of decades of lead particle deposition from vehicular exhaust (NRC 1980; USEPA 1986b). At individual residences, areas affected by leaded gasoline include zones around driveways, garages, and carports and should be taken into account when developing the site conceptual model.

As discuss previously, the concentration of lead detected in a soil or dust sample comprises two parts, as shown schematically in Exhibit 20. That is, there is a site-related component and a non-site related component (e.g., from nearby vehicular traffic). It is prudent to distinguish these sources in order to make cost-effective and health-protective risk management decisions. That is, targeting the wrong environmental media for remediation may not have the intended effect of reducing PbB levels. For example, nearby automobile exhaust resulting in high lead concentrations detected in soil and dust samples at a residence may unknowingly be interpreted as being derived from site-related activities.

EXHIBIT 20

THE SAMPLE LEAD CONCENTRATION IS MADE UP OF TWO PARTS



Exhaust lead is discharged in forms of halides and oxides that are eventually converted to the sulfate. These forms should be distinguished from other site-specific sources of lead based on the ratios of each chemical as defined by the empirical molecular formula.

Rural Areas

Exhibit 21 (adapted from USEPA 1995b) presents information on anthropogenic background lead levels in agricultural areas. Although anthropogenic background conditions are most often associated with organic contaminants resulting from industrialized activities in urban areas, many rural areas in the United States have high concentrations of soil lead. Large rural areas were contaminated during widespread agricultural pesticide application (i.e., crop dusting). Thus, background analyses in rural areas (far removed from urban industrial activities) can be confounded by the presence of anthropogenic background lead. Sites located in areas previously used for agriculture or close to existing agricultural operations must be carefully evaluated. Elevated lead concentrations in these areas may represent normal and routine historical agricultural practices. For example, Exhibit 21 shows that land farming sludges can increase the naturally occurring lead concentrations by thousands of parts per million.

EXHIBIT 21

AGRICULTURAL SOURCES OF ANTHROPOGENIC CHEMICALS

Anthropogenic Source	Concentration Range (mg/kg)
Sewage Sludges	**50-3,000**
Phosphate Fertilizers	**7-225**
Limestones	**20-1,250**
Nitrogen Fertilizers	**2-27**
Manure	**6.6-15**
Pesticides	**600,000**

Source: USEPA, 1995b

Background Airborne Lead

Although lead is not volatile, it can be bound to small particles in air. Some of these particles may be small enough to reach the lung, where, depending on the chemical form, lead may be absorbed into the body. Airborne sources of lead are used in multi-pathway lead risk assessment models, including the *IEUBK* and Ca*LS* models. It should be noted, however, that under most circumstances lead exposure via the inhalation route is very small compared with other routes of exposure. Despite the relative insignificance of airborne lead in directly contributing to elevated PbB levels, it is important to determine whether historical anthropogenic airborne sources significantly contributed to soil and dust loading. For example, airborne lead has historically affected urban soil and dust levels, and can contribute to the concentration detected in samples collected in the drip zone.

There are several up-to-date sources of information on current and historical ambient airborne

lead levels. One of the most complete and detailed is the USEPA Aerometric Information and Retrieval System (AIRS), which can be accessed through the AIRS*Data* Internet site (www.epa.gov/airsdata/monreps.htm). This site provides air pollution data for the entire United States. AIRS*Data* can be used to create regional reports and maps, and it provides contact names for additional information. The database is updated on a monthly basis so that current site-specific information can be used in the lead risk assessment.

3.9 USEPA Integrated Exposure Uptake Biokinetic (IEUBK) Model

3.9.1 Background

The *IEUBK* model is used to predict PbB levels in children during the first 6 years of age. Although lead in soil is a principal focus of the model, a high soil lead concentration by itself does not necessarily cause elevation of PbB levels. Indeed, studies have shown residents chronically exposed to soil lead levels far in excess of 1,000 milligrams per kilogram (mg/kg) to have measured PbB levels within the normal background range. If this concentration had been used in the risk assessment to predict PbB levels, the *IEUBK* model would have been overly conservative. Although a detailed analysis of the *IEUBK* model has not isolated the factors responsible for over predicting PbB levels, it appears that, under some exposure conditions, soil and lead concentrations may not always be good predictors of actual site-specific PbB levels as measured in blood samples in children. Although the model has not yet been thoroughly verified, USEPA (1994b) has concluded:

- *"The model is biologically and physically plausible and incorporates the best available empirical data and parameters";*
- *"The model uses numerically accurate algorithms and the accuracy of the computer codes for these algorithms has been verified"; and*
- *"The model provides some satisfactory empirical comparisons of model output with real-world data."*

While the *IEUBK* model has been used extensively, the computer code has never been released for external review or public comment to verify the computer code or algorithms; and while USEPA has concluded that the *IEUBK* model provides "some satisfactory" PbB predictions when

compared with actual "real-world data," other studies have shown that the model significantly overpredicts lead risks when compared with measured PbB levels. USEPA has intentionally developed the *IEUBK* model to be health protective at all lead-contaminated sites. That is, the conservatism introduced into the risk estimate and subsequent risk management decisions based solely on the *IEUBK* results will always protect the general public. What is not clear is how often, to what degree, and under what circumstances the *IEUBK* model will over predicts risks. True model validation and verification can only be accomplished when blood samples are collected from the child population and PbB levels are determined in exposed children. In situations where the empirical comparisons do not validate the model, USEPA has concluded that it is due to incorrect or inappropriate input parameters that are not site-specific. Although this point correctly emphasizes the need for collecting relevant site-specific information (instead of relying on default values), it does not address the inherent mathematical problem of a deterministic approach where single input parameters are used to predict PbB levels.

There are four possible explanations for discrepancies between measured and predicted PbB levels using the *IEUBK* model, which are as follows:

- Default input parameters are not appropriate and representative;
- The IEUBK model, which is deterministic, does not address normal variability; and
- PbB levels data is not being collected from a "truly representative population" (measured PbB levels are not representative).

Default input parameters to predict PbB levels should only be used as a first approximation of "plausible" PbB levels. Moreover, they should only be used during the initial screening of the site. Considerable conservatism has been built into developing default parameters, and they can significantly overestimate PbB levels.

Despite potential problems with over predicting PbB levels, the *IEUBK* model has been recommended as the risk assessment tool to support the implementation of the July 14, 1994, Office of Solid Waste and Emergency Response Interim Directive on Revised Soil Lead Guidance for CERCLA Sites and RCRA Facilities. The most current version, Version 0.99D of the *IEUBK* model, is used in this risk analysis.

3.9.2 Technical Description—Model Overview

The *IEUBK* model is used to predict blood lead concentrations in children. Using relevant input parameters, the *IEUBK* rapidly calculates the PbB level by solving a complex set of equations to estimate PbB levels for a hypothetical child or population of children (where a childhood exposure is assumed to occur from 6 months to 7 years of age). It calculates a plausible distribution of PbB levels centered on the geometric mean PbB level using a default value for the geometric standard deviation. From this distribution, the model calculates the probability that children's PbB levels will exceed the 95 percentile PbB levels. The current USEPA (1998a) risk management goal is to limit exposure so that there is a less-than-5% probability that PbB levels will exceed 10 μg/dL in a population of children.

It should be noted that USEPA (1994b) emphasizes the *IEUBK* model has several limitations. For example, it should not be used to model exposure periods of less than three months or when exposures are intermittent (exposures occur significantly less than 7 days per week). The model assumes steady-state chronic exposure conditions. USEPA cautions against interpreting the results of the *IEUBK* model as matching the PbB levels for a *specific* child. The model is designed to predict an average PbB concentration for an entire population or the probability that a child with a specific exposure scenario would have an elevated PbB level. The model cannot accurately predict PbB levels for short, occasional, or transitory lead exposures. Most importantly, the model cannot predict PbB levels associated with direct ingestion of paint chips. However, under conditions where leaded paint is deteriorating and soil and dust lead loading is occurring, the *IEUBK* model indirectly estimates the leaded paint by incorporating soil and dust lead levels directly into the risk assessment. Finally, when using the *IEUBK* model, it is important to distinguish naturally occurring and anthropogenic contributions of lead exposure. unless steps are taken to differentiate site-specific and background lead concentrations.

The IEUBK model is used to predict exposure associated with all lead-contaminated environmental media; air, water, soil, dust, and diet. The model has the following four functional components:

- **Exposure Component:** Compares lead concentrations in environmental media with the amount of lead intake. The exposure component utilizes environmental media-specific intake rates and lead concentrations in each environmental medium to estimate media-specific lead intake.
- **Uptake Component:** Compares lead intake into the lungs or digestive tract with the amount of lead absorbed into the child's blood.

- **Biokinetic Component:** Evaluates transfer of lead between blood and other body tissues, and the elimination of lead from the body altogether.

- **Probability Distribution Component:** Reveals the probability that PbB levels will exceed 10 µg/dL in an exposed child based on default or site-specific parameters used in the model.

A site-specific risk assessment requires gathering exposure information on lead from all possible environmental media for the site. For example, information on lead exposure from soil and dust includes soil-to-indoor dust transfer; ingestion parameters for soil and dust (i.e., how much soil or dust a typical child may ingest over the exposure duration); and the amount of lead that can be absorbed from the soil and dust. Risk estimates are very sensitive to these input parameters, and changing a single input parameter for a variable can significantly affect the predicted PbB levels.

Although the *IEUBK* model is primarily designed to calculate the risk of elevated PbB levels, it can also be used to determine how a specific remedial action may reduce site PbB levels to acceptable levels. By entering the target remediation levels or projected cleanup goals, the *IEUBK* model can be used to predict PbB levels following remediation. Used iteratively in this manner, the model can narrowly focus risk management decisions on efforts to mitigate lead risks that will be truly effective.

Although the *IEUBK* model requires input for all potential lead exposure pathways associated with all lead-impacted environmental media, the only absolute requirement for *site-specific* input is the average soil lead concentration. For all other environmental media, default parameters have been developed by USEPA; however, before automatically using default parameters, a careful evaluation of the default parameters should be conducted. For this reason, it is desirable to use default parameters in the *IEUBK* model only during a *screening* risk assessment. Sites that fail the initial screen should then be further investigated by collecting site-specific data to re-run the *IEUBK* model using data to more accurately capture site-specific conditions.

The risk assessment must clearly identify and communicate all the assumptions and uncertainties associated with the predicted PbB levels. When there is considerable uncertainty in the lead risk assessment, cost-effective recommendations should be made to eliminate or reduce uncertainty to the extent possible. This is particularly true for the input parameters to which the *IEUBK* model is very sensitive. It is as important to identify the key site-related variables and assumptions that contribute most to the uncertainty, as it is to precisely quantify the degree of uncertainty in predicted PbB levels.

Although the *IEUBK* model can be used to predict the average PbB level for an entire community, there may be significant variability within the exposed population between different homes within a single community. At these sites, it would be prudent to first apply the *IEUBK* model to predict PbB levels for individual homes or homogeneous areas, then to combine the results to derive the mean or average PbB levels for the neighborhood or community.

According to USEPA (1994b), the *IEUBK* model is intended to:

- Evaluate a typical child's *long-term* exposure to lead in and around the residence;
- Predict a plausible estimate of the geometric average PbB level for a typical child aged 6 months to 7 years;
- Estimate the *risk* of elevated PbB levels for a hypothetical child;
- Evaluate the impact of *remediation* on the risk of elevated PbB levels by using proposed remediation target goals in soil, dust, water, or air in the model;
- Determine final target cleanup levels at specific residential sites for soil or dust containing high amounts of lead; and
- Provide support assistance in estimating PbB levels associated with the Pb concentration of soil or dust at undeveloped sites that may be developed at a later date.

3.9.3 Input Parameters

Default input parameters are descriptive statistics based on U.S. population census data and scientific studies representing the general childhood population. For example, it is impossible to precisely determine the amount of soil and dust a child ingests; how much is actually absorbed into the body; and how the lead is distributed, stored, and excreted on a daily basis. For this reason, the *IEUBK* model cannot accurately predict the PbB level for a specific child, but rather makes predictions for the average child under the specified conditions. Assumptions made about the target population distribution and variability within the population can then be used to generate a PbB levels for the childhood population in the area under investigation.

Exhibit 22 presents the age-adjusted, USEPA-derived default parameters (built into the computer model) used to predict lead risks with the *IEUBK* model.

EXHIBIT 22

DEFAULT EXPOSURE ASSUMPTIONS FOR USEPA IEUBK MODEL

Medium	Parameter	Age (years)						
		0-1	**1-2**	**2-3**	**3-4**	**4-5**	**5-6**	**6-7**
Air	Breathing Rate (m^3/hr)	2	3	5	5	5	7	7
	Time Outside (hr/day)	1	2	3	4	4	4	4
	Concentration In/Out	0.3	0.3	0.3	0.3	0.3	0.3	0.3
	Absorption Fraction	0.32	0.32	0.32	0.32	0.32	0.32	0.32
	Default Concentration (µg/ m^3)	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Diet	Daily Lead Intake (µg/day)	5.53	5.78	6.49	6.24	6.01	6.34	7.00
	Absorption Fraction	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Drinking Water	Ingestion Rate (L/day)	0.2	0.5	0.52	0.53	0.55	0.58	0.59
	Absorption Fraction	0.5	0.5	0.5	0.5	0.5	0.5	0.5
	Default Concentration (µg/L)	4	4	4	4	4	4	4
Soil/Dust Ingestion	Total Daily Intake (mg/day)	85	135	135	135	100	90	85
	Soil Fraction	0.45	0.45	0.45	0.45	0.45	0.45	0.45
	Dust Fraction	0.7	0.7	0.7	0.7	0.7	0.7	0.7
	Absorption Fraction	0.3	0.3	0.3	0.3	0.3	0.3	0.3
All	Geometric Standard Deviation	1.6	1.6	1.6	1.6	1.6	1.6	1.6

Source: USEPA 1994b

3.9.4 Updated Input Parameters

The default parameters used with regulatory lead models have not been updated for many years. For example, the values presented in USEPA guidance (1994b) are based on various studies that were considered by USEPA to be, at the time, the best available estimates for urban residents with no unusual lead exposure. As additional studies become available, however, it is important to ensure that default values are continuously updated. Default values that were appropriate and representative six years ago may not be applicable today.

The following brief sections highlight the most important default values that need to be updated on a regular basis. The values suggested below accurately represent conditions as of January 2000.

Baseline PbB Levels - As mentioned in Section 1.2, the most recent NHANES III report (Phase 2, 1991-1994; CDC 1997) revealed a marked decrease in PbB levels that USEPA primarily attributes to reduced leaded gasoline use. Overall lead emissions from highway vehicles have decreased the concentration of airborne lead and lead loading to soil. The NHANES II reported the air lead concentration in 1990 was 0.1 $\mu g/m^3$; according to the California Air Resource Board (CARB; 1999), the airborne lead concentration has markedly declined throughout the state of California and is now 0.028 $\mu g/m^3$. Airborne levels are constantly monitored, and the latest data should be used to model lead exposures.

Maternal PbB Levels - The maternal PbB level is used in the *IEUBK* model to establish a baseline PbB level in the neonate. The previous default value based on NHANES II was 2.5 µg/dL. According to the results of NHANES III, Phase 2, this value should be revised to 1.4 µg/dL for women living in the western United States (CDC 1994; Bowers and Cohen 1998).

Lead In Food - The lead concentration in food has decreased primarily due to the ban on lead soldering used in canned goods and the overall reduction of lead in the environment. The reduction is estimated to be 30% from the age-adjusted default values derived by USEPA (1994b), based on recent U.S. Food and Drug Administration (USFDA) Market Basket surveys (Bolger *et al.*1996).

In summary, Exhibit 23 presents the updated age-adjusted default input values for the *IEUBK* model juxtaposed with historical values that can be used to estimate lead risk assessments and cleanup goals. However, it still may be necessary to collect site-specific information to predict more accurate PbB levels. That is, in the absence of site-specific data using these updated parameters, PbB levels should still only be considered a screening risk assessment.

EXHIBIT 23

IEUBK MODEL UPDATED VALUES

PARAMETER	PREVIOUS DEFAULT VALUE	UPDATED VALUE	UNITS
AIR (constant)			
Outdoor Air Lead Concentration	0.10	0.028	$\mu g/m^3$
Ratio Of Indoor To Outdoor Air Lead Concentration	30	30	%
AIR (by year)			
Air Concentration			
Age = 0-1 Year (0-11 Months)	0.10	0.028	$\mu g/m^3$
1-2 Years (12-23 Months)	0.10	0.028	$\mu g/m^3$
2-3 Years (24-35 Months)	0.10	0.028	$\mu g/m^3$
3-4 Years (36-47 Months)	0.10	0.028	$\mu g/m^3$
4-5 Years (48-59 Months)	0.10	0.028	$\mu g/m^3$
5-6 Years (60-71 Months)	0.10	0.028	$\mu g/m^3$
6-7 Years (72-84 Months)	0.10	0.028	$\mu g/m^3$
Time outdoors			
Age = 0-1 Year (0-11 Months)	1	1	h/day
1-2 Years (12-23 Months)	2	2	h/day
2-3 Years (24-35 Months)	3	3	h/day
3-7 Years (36-83 Months)	4	4	h/day
VENTILATION RATE			
Age = 0-1 Year (0-11 Months)	2	2	m^2/day
1-2 Years (12-23 Months)	3	3	m^2/day
2-3 Years (24-35 Months)	5	5	m^2/day
3-4 Years (36-47 Months)	5	5	m^2/day
4-5 Years (48-59 Months)	5	5	m^2/day
5-6 Years (60-71 Months)	7	7	m^2/day

6-7 Years (72-84 Months)	7	7	m^2/day
Lung Absorption	32	32	%
DIET INTAKE			
Dietary Lead Intake			
Age = 0-1 Year (0-11 Months)	5.53	3.87	µg Pb/day
1-2 Years (12-23 Months)	5.78	4.04	µg Pb/day
2-3 Years (24-35 Months)	6.49	4.54	µg Pb/day
3-4 Years (36-47 Months)	6.24	4.37	µg Pb/day
4-5 Years (48-59 Months)	6.01	4.21	µg Pb/day
5-6 Years (60-71 Months)	6.34	4.44	µg Pb/day
6-7 Years (72-84 Months)	7.00	4.90	µg Pb/day
ALTERNATE DIET SOURCES			
Concentration:			
Home-Grown Fruits	0	0	µg Pb/g
Home-Grown Vegetables	0	0	µg Pb/g
Fish From Fishing	0	0	µg Pb/g
Game Animals From Hunting	0	0	µg Pb/g
Percent Of Food Class			
Home-Grown Fruits	0	0	%
Home-Grown Vegetables	0	0	%
Fish From Fishing	0	0	%
Game Animals From Hunting	0	0	%
DRINKING WATER			
Lead Concentration In Drinking Water	4	4	µg/L
Ingestion Rate			
Age = 0-1 Year (0-11 Months)	0.20	0.20	Liters/day
1-2 Years (12-23 Months)	0.50	0.50	Liters/day
2-3 Years (24-35 Months)	0.52	0.52	Liters/day
3-4 Years (36-47 Months)	0.53	0.53	Liters/day

4-5 Years (48-59 Months)	0.55	0.55	Liters/day
5-6 Years (60-71 Months)	0.58	0.58	Liters/day
6-7 Years (72-84 Months)	0.59	0.59	Liters/day
DRINKING WATER SOURCES			
Concentration:			
First-Draw Water	4	4	µg/L
Flushed Water	1	1	µg/L
Fountain Water	10	10	µg/L
Percentage Of Total Intake			
First-Draw Water	50	50	%
Flushed Water (not a user entry; calculated based on entries for first-draw and fountain percentages)	100 minus first draw and fountain	100 minus first draw and fountain	%
Fountain Water	15		%
SOIL/DUST LEAD (constant)			
Concentration:			
Soil	200	530	µg /g
Dust	200	374	µg /g
Soil Ingestion As Percent Of Total Soil And Dust Ingestion	45	45	%
SOIL/DUST INGESTION			
Soil/Dust Ingestion Rate			
Age = 0-1 Year (0-11 Months)	0.085	0.085	g/day
1-2 Years (12-23 Months)	0.135	0.135	g/day
2-3 Years (24-35 Months)	0.135	0.135	g/day
3-4 Years (36-47 Months)	0.135	0.135	g/day
4-5 Years (48-59 Months)	0.100	0.100	g/day
5-6 Years (60-71 Months)	0.090	0.090	g/day
6-7 Years (72-84 Months)	0.085	0.085	g/day
SOIL LEAD			

Soil Lead Concentration			
Age = 0-1 Year (0-11 Months)	200	530	Mg/g
1-2 Years (12-23 Months)	200	530	Mg/g
2-3 Years (24-35 Months)	200	530	Mg/g
3-4 Years (36-47 Months)	200	530	Mg/g
4-5 Years (48-59 Months)	200	530	Mg/g
5-6 Years (60-71 Months)	200	530	Mg/g
6-7 Years (72-84 Months)	200	530	Mg/g
DATA ENTRY FOR DUST			
Dust Lead Concentration			
Age = 0-1 Year (0-11 Months)	200	374	Mg/g
1-2 Years (12-23 Months)	200	374	Mg/g
2-3 Years (24-35 Months)	200	374	Mg/g
3-4 Years (36-47 Months)	200	374	Mg/g
4-5 Years (48-59 Months)	200	374	Mg/g
5-6 Years (60-71 Months)	200	374	Mg/g
6-7 Years (72-84 Months)	200	374	Mg/g
SOIL/DUST MULTIPLE SOURCE ANALYSIS (constant)			
Ratio Of Dust Lead Concentration To Soil Lead Concentration	0.70	0.70	Unitless
Ratio Of Dust Lead Concentration To Outdoor Air Lead Concentration	100	100	µg Pb/g dust per µg Pb/m^3 air
SOIL/DUST MULTIPLE SOURCE ANALYSIS WITH ALTERNATIVE HOUSEHOLD DUST LEAD SOURCES (constant)			
Concentration			
Household Dust (Calculated)	Site-Specific	Site-Specific	mg/g
Secondary Occupational Dust	Site-Specific	Site-Specific	mg/g
School Dust	Site-Specific	Site-Specific	mg/g
Daycare Center Dust	Site-Specific	Site-Specific	mg/g

Second Home	Site-Specific	Site-Specific	mg/g
Interior LBP	Site-Specific	Site-Specific	mg/g
Percentage			
Household Dust (Calculated)	100 minus all other	100 minus all other	%
Secondary Occupational Dust	0	0	%
School Dust	0	0	%
Daycare Center Dust	0	0	%
Second Home	0	0	%
Interior LBP	0	0	%
BIOAVAILABILITY FOR ALL GI ABSORPTION PATHWAYS			
Total lead absorption (at low intake)			
Diet	50	50	%
Drinking Water	50	50	%
Soil	30	30	%
Dust	30	30	%
Alternate Source	0	0	%
Fraction Of Lead Absorbed Passively At High Intake			
Diet	0.2	0.2	Unitless
Drinking Water	0.2	0.2	Unitless
Soil	0.2	0.2	Unitless
Dust	0.2	0.2	Unitless
Alternate Source	0.2	0.2	Unitless
ALTERNATE SOURCES (by year)			
Total Lead Intake			
Age = 0-1 Year (0-11 Months)	0	0	µg/day
1-2 Years (12-23 Months)	0	0	µg/day
2-3 Years (24-35 Months)	0	0	µg/day
3-4 Years (36-47 Months)	0	0	µg/day

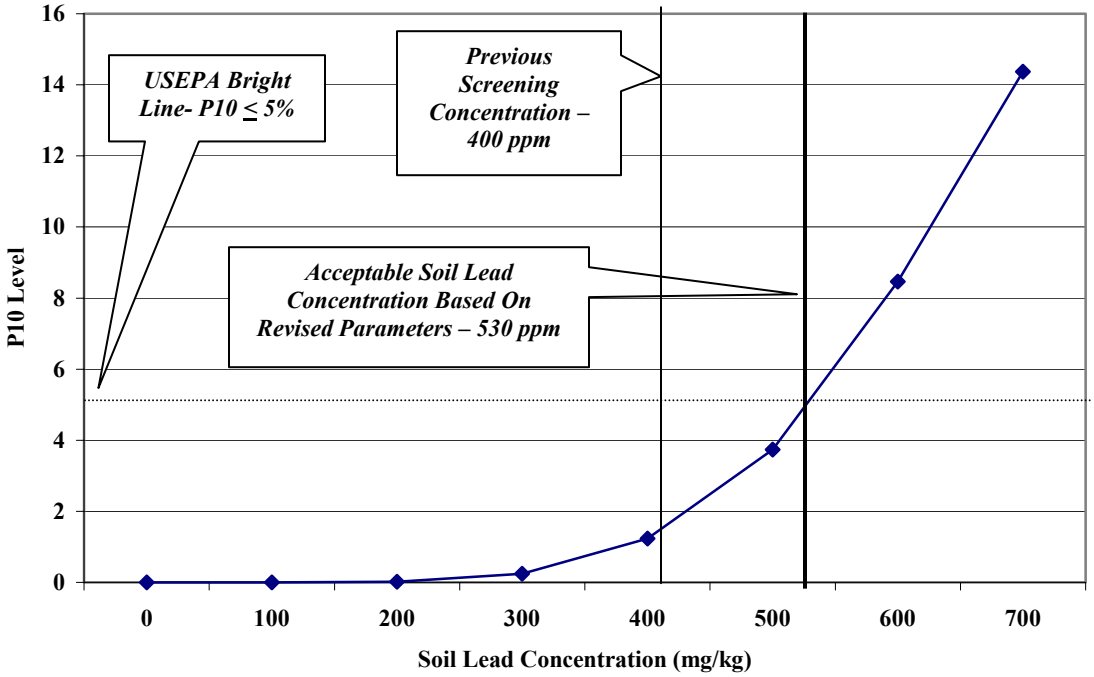
4-5 Years (48-59 Months)	0	0	µg/day
5-6 Years (60-71 Months)	0	0	µg/day
6-7 Years (72-84 Months)	0	0	µg/day
MATERNAL-TO-NEWBORN LEAD EXPOSURE			
Mother's Blood Lead Level At Time Of Birth	2.5	1.4	mg/dL
PLOTTING AND RISK ESTIMATION			
Geometric Standard Deviation For Blood Lead, GSD	1.6	1.4	Unitless
Blood Lead Level Of Concern, Or Cutoff	10	10	Mg/dL
COMPUTATION OPTIONS			
Iteration Time Step For Numerical Integration	4	4	h

Note: Updated values were current as of January 2000.

Exhibit 24 presents P10 levels corresponding to increasing soil lead concentrations using the updated values. To calculate cleanup goals, the same revised input values are entered into the model, and the model is used iteratively until the target acceptable P10 level (where the P10 is equal to 5 percent) is calculated. As shown, the updated default soil acceptable concentration is 530 ppm.

EXHIBIT 24

IEUBK-PREDICTED P10 LEVELS CORRESPONDING TO INCREASED SOIL LEAD CONCENTRATION BASED ON REVISED DEFAULT PARAMETERS



3.10 USEPA Adult Lead Model

3.10.1 Background

In December 1996, the USEPA Technical Review Workgroup prepared a guidance document titled *"Recommendations of the Technical Review Workgroup for Lead for an Interim Approach to Assessing Risks Associated with Adult Exposures to Lead in Soil,"* which presents tools that can be used in a risk assessment to provide an evaluation of risk for sites with occupational exposures. Although termed the "adult" model, the exposed receptor is actually a hypothetical *fetus*. That is, the approach developed in the *AL* Model for predicting PbB levels for adult receptors relates the amount of soil lead ingested by a hypothetical pregnant woman to a corresponding PbB level in her developing fetus. Thus, the default assumption is that all non-residential sites will have worker populations with at least one woman who will become pregnant while employed at the site and continue to regularly work at the site through her pregnancy for at least three continuous months. During the gestational period, the fetus will be exposed to lead in soil as a result of the woman coming into direct contact with lead and the mother's PbB levels will reach a "quasi-steady state" via placental lead transfer. As with children, USEPA policy has established a safe PbB level of less than 5 percent of fetuses with PbB levels greater than 10 µg/dL. It should be noted that this brightline is based on supporting empirical data on safe PbB levels in the fetus. They may be higher or lower. In summary, USEPA has concluded (1999a):

> *"Based on the available scientific information, a fetus is believed to be more sensitive to the adverse affects of lead than an adult. Thus, preliminary remediation goals (PRGs) that are protective of a fetus should also afford protection for adults."*

Although this conclusion appears reasonable, it is also reasonable to conclude, based on behavioral and physiological differences, that site conditions protecting the fetus are *overprotective* of an adult worker population. This is particularly true in occupations where the likelihood of fetal exposure is negligible (either due to a low probability of a woman of

childbearing age being employed or employed-exposed-and pregnant for three months).

3.10.2 Technical Description—Model Overview

Unlike the *IEUBK* model, the *AL* model is a simple lead model based on a slope factor approach. It does not attempt to evaluate important biokinetic aspects of lead exposure (as does the *IEUBK* model for children). Instead of estimating PbB levels based on empirical information on lead biokinetics—which includes absorption, distribution, transformation, and excretion—it simply relates PbB levels to the amount of lead ingested from soil. In estimating PbB levels for a pregnant woman (assumed to be directly exposed to site-specific soil lead concentrations), the incremental increase in the PbB level resulting from site-specific conditions is simply added to the "baseline" PbB level assumed to already exist in the pregnant woman as a result of background lead levels.

The *AL* model is a two-step process:

- **Step 1:** Calculate PbB levels in an occupationally exposed pregnant woman.
- **Step 2:** Extrapolate the PbB level in the pregnant woman to her fetus.

In the first step, the PbB level for a hypothetical pregnant women is estimated. The predicted PbB level for the pregnant women is made up of the following two components:

- **Non-site Related Background (or Baseline Lead Sources):** Store-bought food, ambient air, home tap water, etc.; and
- **Site-related Sources of Lead (Site Exposures):** Site-specific lead in soil and dust.

The following equation is used to estimate PbB levels in an occupationally exposed pregnant woman:

$$PbB_{adult,\,central} = PbB_{adult,\,0} + \frac{PbS \times BKSF \times IR_S \times AF_S \times EF_S}{AT}$$

Where:

$PbB_{adult, central}$ = Average PbB level (µg/dL) in a hypothetical occupationally exposed pregnant woman who contacts lead at the site.

$PbB_{adult, 0}$ = Background (or baseline) PbB level (µg/dL) in the pregnant woman (representing lead exposures away from the site being assessed).

PbS = Site-specific soil lead concentration (µg/g; average concentration contacted daily).

$BKSF$ = Biokinetic slope factor relating the increase in PbB level in the pregnant woman to average daily lead uptake (µg/dL PbB increase per µg/day lead uptake).

IR_S = Soil intake rate by a pregnant woman (g/day; including both outdoor soil and indoor soil-derived dust).

AF_S = Absolute gastrointestinal absorption fraction for ingested lead in soil and dust.

EF_S = Exposure frequency for soil and dust contact (days of exposure during the averaging period).

AT = Averaging time; the total period during which soil contact may occur; 365 days/year for continuing long-term exposures.

The second step is to relate the calculated PbB level in the pregnant woman (calculated above; $PbB_{adult, central}$) to the fetus. It is assumed that the fetus will be carried to term while the pregnant mother is exposed to site lead in soil and dust. In other words, the PbB level has reached a quasi-steady state (it does not address intermittent or short exposures). The following equation is used to predict how much lead is transferred from the mother's blood into the fetus.

$$PbB_{fetal, 0.95} = PbB_{adult, central} * GSD^{1.645}_{i, adult} * R_{fetal/maternal}$$

Where:

$PbB_{adult, central\ goal}$ = Goal for average PbB levels (µg/dL) in pregnant women. The

goal is intended to ensure that $PbB_{fetal, 0.95}$, does not exceed 10 µg/dL.

$\boldsymbol{PbB_{fetal, 0.95, goal}}$ = Goal for the 95th percentile PbB level (µg/dL) among exposed fetuses. This is interpreted to mean that the likelihood of a fetal PbB level greater than 10 µg/dL would be less than 5%.

$\boldsymbol{GSD_{i, adult}}$ = Estimated value of the geometric standard deviation among women of childbearing age. The exponent, 1.645, is the value of the standard normal deviate used to calculate the 95th percentile from a lognormal distribution of PbB level.

$\boldsymbol{R_{fetal/maternal}}$ = Ratio between fetal PbB levels ($PbB_{fetal, 0.95}$) at birth and maternal PbB levels ($PbB_{adult, central}$; unitless).

The scientific veracity of predicting fetal PbB levels with the *AL* model and the appropriateness of USEPA policy for evaluating non-residential lead exposure are based on the following limitations and default assumptions:

Within each non-residential worker population, at least one woman will be employed who will become pregnant and continue to work at the site during her pregnancy;

- It is scientifically correct to estimate the PbB level in a pregnant woman as the sum of an expected starting PbB level in the absence of site exposure ($PbB_{adult, 0}$) and an expected site-related increase resulting from exposure to the site;
- The site-related increase in PbB levels is linear over the entire exposure range and can be estimated using a linear biokinetic slope factor;
- Lead uptake in the pregnant woman is *directly* related to the estimated soil lead concentration (Pb_S), the overall rate of daily soil ingestion (IR_S), and the estimated fractional absorption of ingested lead (AF_S);
- The distribution of PbB levels in the subpopulation of pregnant women in the United States is lognormal and is appropriate to use at any U.S. site; and

- The expected fetal PbB levels are *directly proportional* to maternal PbB levels in all cases, and they are lognormally distributed with a standard deviation identical to the subpopulation of PbB levels among women of childbearing age.

3.10.3 Input Parameters

As indicated in the above section, the *AL* model is a simplistic risk assessment model that simply adds the PbB level resulting from one exposure pathway, namely soil ingestion, to the baseline (background) PbB levels. Based on recent information, some default values used in the original model should be updated. Default values are presented in Exhibit 25.

EXHIBIT 25

SUMMARY OF DEFAULT AL MODEL INPUT PARAMETERS

INPUT PARAMETER	DEFAULT VALUE	PARAMETER DESCRIPTION
$PbB_{fetal,\ 0.95,goal}$	10 µg/dL	***Target PbB:*** PbB goal of likelihood of a fetal PbB level greater than 10 µg/dL would be less than 5%.
$GSD_{i,adult}$	1.8 or 2.1	***Geometric Standard Deviation***
$R_{fetal/maternal}$	0.9 µg/dL	***Ratio Between Fetal and Maternal Blood***
$PbB_{adult,0}$	1.7-2.2 µg/dL	***Background/Baseline PbB Levels***
BKSF	0.4 µg/dL per µg/day	***Biokinetic Slope Factor***
IR_S	0.05 g/day	***Ingestion Rate***
EF_S	219 day/yr	***Exposure Frequency***
AF_S	0.12 (unitless)	***Absorption Factor***

3.10.4 Revised Default Input Parameters

It is important to note that default parameters are based on U.S. population statistics and should not be considered site-specific values. Consequently, predicted PbB levels based on default

values should be considered screening levels. It is highly recommended that site-specific information be collected and used to precisely predict PbB levels.

The following brief section provides supporting rationale for revising some input parameters suggested in previous USEPA guidance. The suggested changes are based on recent studies and information that has become available since the time the original guidance was prepared.

Geometric Standard Deviation - It is important to correctly estimate or define the GSD when predicting PbB levels in the fetus because it is used directly to estimate $PbB_{fetal,95}$, which is defined as the 95th percentile PbB levels among fetuses born to women exposed to site-specific lead concentrations. The $PbB_{fetal,95}$ is estimated with the following equation:

$$PbB_{fetal,0.95} = R_{fetal/maternal} * PbB_{adult,central} * GSD^{1.645}$$

A small change in the GSD can translate to a significantly different $PbB_{fetal,0.95}$ level. The previous GSD values of 1.8 to 2.1 were based on the results of the NHANES III, Phase 1 study. (Brody *et al.* 1994). According to White *et al.* (1998), the previous default GSD values of either 1.8 or 2.1 should be revised to 1.6. The authors state:

> *"The recommended default GSD for the IEUBK model is 1.6, which is intended as a broadly applicable, not a conservative, value."*

However, when possible, the GSD should be estimated based on empirical data. For Western states (including California), the NHANES III study shows a GSD of 1.4 is more representative than 1.6 and should be used where appropriate.

Baseline PbB Levels - The baseline PbB level ($PbB_{adult,0}$) is intended to represent the best estimate of the average PbB level in women of childbearing age who are not exposed to lead at the site. It is important to accurately define $PbB_{adult,0}$ in predicting PbB levels for a non-residential lead exposure scenario because the predicted PbB_{adult} is defined as the sum of PbB levels corresponding to baseline (from background sources) and site-specific sources of lead:

$$PbB_{Total} = Pb_{Adult,0} + Pb_{Site\text{-}Specific}$$

The value used to represent $PbB_{adult,0}$ should be based on an estimate of the target population at the site. However, this information is not always available. The best estimate of $PbB_{adult,0}$ is

based on a representative population of adult women not exposed to site soil or dust, but who are exposed to naturally occurring and ubiquitous background lead. In cases where site-specific extrapolations from surrogate populations are not possible, USEPA previously recommended a GSD of 1.7 to 2.2 µg/dL as a plausible range, based on the results of Phase 1 of the NHANES III, as reported by Brody *et al.* (1994). Based on the results of NHANES III, Phase 2, this value should be revised to 1.4 µg/dL for women living in the western United States (CDC 1994; Bowers and Cohen 1996; CDC 1997). Exhibit 26 presents updated summary information of Phase 1 and 2 NHANES III data for women of childbearing age based on different U.S. regions.

EXHIBIT 26

SUMMARY BASELINE PBB LEVELS FOR WOMEN OF CHILDBEARING AGE IN DIFFERENT REGIONS OF THE UNITED STATES

	PHASE-1 NHANES III (1)		PHASE-2 NHANES III (2)	
U.S. REGION	**GEOMETRIC MEAN**	**GEOMETRIC STANDARD DEVIATION**	**GEOMETRIC MEAN**	**GEOMETRIC STANDARD DEVIATION**
Midwest	**1.84**	**1.94**	**1.48**	**1.89**
Northeast	**2.39**	**1.82**	**1.74**	**1.76**
South	**1.54**	**1.88**	**1.42**	**1.77**
West	**1.77**	**1.83**	**1.36**	**1.81**

(1) Phase-1 NHANES III data represent baseline PbB levels during years 1988-1991.
(2) Phase-2 NHANES III data represent baseline PbB levels during years 1991-1994.

Ingestion Rate - The ingestion rate represents the *average* amount (gm/day) of soil and dust (derived from soil) ingested by women of childbearing age. USEPA (1999b) recommends a default value of 0.05 g/day as a plausible point estimate of the central tendency for daily soil intake from all occupational sources, including soil in indoor dust, resulting from non-contact-intensive activities. The Agency suggests that site-specific data on soil contact intensity, including potential seasonal variations, be considered in evaluating whether or not the default value is applicable to the population of concern and, if not, that activity-weighted estimates of IR_S

that more accurately reflect the site be developed.

Little empirical information is available to estimate adult ingestion rates because most soil ingestion studies have been conducted for children. A study by Stanek and Calabrese (1995) indicates that the average ingestion rate for a child is 0.04 g/day. Based on the assumption that children have a much higher ingestion rate than adults (due to hand-to-mouth behaviors), it is reasonable to assume that, for normal indirect contact with soil, an adult would ingest approximately 50% of the amount ingested daily by a child (Bowers and Cohen 1996). Based on this proportionality, an average daily ingestion rate of 0.02 g/day for an adult woman of childbearing age who works primarily indoors is appropriate. However, for higher-intensity exposures for outdoor workers who directly contact soil, the USEPA default value of 0.05 g/day likely represents the appropriate average daily ingestion rate.

Additional Adjustments - Two additional adjustments to the *AL* model are necessary to estimate site-specific PbB levels for a non-residential indoor worker. They are as follows:

- Converting external soil concentrations to indoor dust concentrations; and
- Adjusting the daily soil ingestion rate to differentiate soil ingested from the site from soil ingested off-site.

Developing Indoor Dust Concentrations for Indoor Workers - In the past, USEPA has grouped all non-residential exposures under the general heading of occupational scenarios without making important distinctions about potential differences in work-related activities. For example, a clerical worker who spends the entire workday in a climate-controlled office would be exposed to far less soil and dust lead than a construction worker or landscaper. When soil lead is the only source of lead exposure, indoor workers would be exposed to indoor dust.

USEPA (2001) guidance now provides an approach for evaluating risks associated with different types of occupational exposures. As presented in *"Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites,"* health-protective screening levels for numerous chemicals can be developed for two general non-residential classifications based on different work-related activity patterns for the following groups:

- Indoor workers; and
- Outdoor worker/landscapers.

According to USEPA, an indoor worker is defined as:

> ***Indoor Worker:*** *This receptor spends most, if not all, of the workday indoors. Thus, an indoor worker has no direct contact with outdoor soils. This worker may, however, be exposed to contaminants through ingestion of contaminated soils that have been incorporated into indoor dust, ingestion of contaminated ground water, and the inhalation of contaminants indoors through vapor intrusion. SSLs calculated for this receptor are expected to be protective of both workers engaged in low intensity activities such as office work and those engaged in more strenuous activity (e.g.,. factory or warehouse workers).*
>
> ***Outdoor Worker:*** *This is a long-term receptor exposed during the work day who is either: (1) a full time employee of the company operating on-site who spends most of the workday landscaping or conducting other maintenance activities outdoors; or (2) who is assumed to return regularly to the site for grounds-keeping activities. The activities for this receptor (e.g., moderate digging, gardening) typically involve on-site exposures to surface and shallow subsurface soils (at depths of zero to two feet). The outdoor worker/landscaper is expected to have a high soil ingestion rate and is assumed to be exposed to contaminants via the following pathways: dermal contact, inhalation of volatiles outdoors, inhalation of fugitive dust, incidental ingestion of soil, and ingestion of ground water contaminated by leachate. The outdoor worker/landscaper is expected to be the most highly exposed receptor in the outdoor environment under commercial/industrial conditions. Thus SSLs for this receptor are protective of other reasonably anticipated outdoor activities at commercial/industrial facilities.*

For office workers exposed to indoor dust at sites with no separate indoor source of lead contamination, it can be assumed that dust lead is derived entirely from outdoor soil. Dust lead loading occurs either through-resuspended soil in air or by being directly transported into the building on contaminated clothing or shoes. At many sites, the dust lead concentration indoors is only a fraction of the outdoor soil concentration. Using the soil lead concentration to estimate lead risks for indoor workers significantly overestimates exposure and PbB levels. To make accurate PbB level estimates for indoor workers, it is necessary to base predictions on the amount of lead ingested from dust.

USEPA has found that the physical relationships between soil and dust are complex and may or

may not be related. Their results, presented in *"Data Analysis of Lead in Soil and Dust"* (USEPA 1993) suggest that the expected correlation between soil and dust is not always empirically observed. Nonetheless, it is imperative to base PbB level predictions on accurate site-specific dust lead concentrations. For indoor workers, it is preferable to collect indoor dust samples that can be used directly in the *AL* model by substituting dust for soil concentration. The following equation describes the relationship between soil and dust lead concentration.

$$\boldsymbol{PbD = PbS * M_{SD}}$$

Where:

PbD	=	Average indoor dust lead concentration (µg/g).
PbS	=	Average soil lead concentration (µg/g).
$\boldsymbol{M_{SD}}$	=	Mass fraction of soil in dust (g soil/g dust).

This equation expresses the relationship between indoor lead dust and outdoor soil, and assumes there is no other site-specific source of lead (most notably, leaded paint). Although the most precise estimates of PbB levels for non-residential receptors are based on empirical measurements of lead dust within the office where exposures will occur, it is not always practical or cost-effective to collect dust samples. Where site-specific data is not available, USEPA has developed a default value of 0.70 for M_{SD} based on paired sampling (dust and soil lead) for residential housing. This default value was developed for the *IEUBK* model to describe the empirical relationship between soil and dust lead concentrations, based on measurements in a variety of residential communities (USEPA 1994b). However, further studies are needed to confirm the magnitude of the mass movement of soil indoors, particularly into office space. Although many studies have focused on the relationship of dust and soil lead in residential housing, detailed studies for office buildings do not exist.

The M_{SD} for residential exposure is strongly influenced by factors that affect soil deposition rates indoors, including the following:

- The number of children and pets that may track soil indoors;
- Environmental factors, such as climate (e.g., local rain and wind patterns);
- The extent of vegetative cover of residential yards;
- The deposition of soils transported from neighboring properties; and

- Use of dust control measures, such as frequent cleaning, removing shoes at the entryway, etc. (Roberts and Dickey 1995).

Similar contributors to indoor lead dust are not present at office buildings, resulting in lower indoor lead dust concentrations. For example, while children and pets playing outdoors in soil lead would be expected to contribute significantly to dust levels, these would not be factors for the indoor worker. Moreover, office workers typically walk (after parking their cars) on pavement to the office doors without directly contacting soil lead. The landscaping around office buildings is also typically maintained with ground cover that would reduce soil resuspension. For these reasons, the concentration of dust lead in office buildings is likely to be much lower than that in a residential housing unit. However, because no default M_{SD} value for office buildings has yet been developed, there is little choice but to use the residential M_{SD} value in the absence of site-specific empirical dust lead data.

Adjusting the On-Site Lead Soil Ingestion Rate - The ingestion rate for non-residential adult exposures is based on the amount of soil and dust ingested per day. Not all soil ingested each day is attributable to site soil and dust. Consequently, the ingestion rate must be adjusted to represent soils ingested at the site. On average, an occupational receptor is assumed to be exposed 8 hours on-site while at work and 16 hours off-site (8 of which are assumed to be spent sleeping, when no soil ingestion occurs). Thus, only 50% of the soil/dust ingested on a daily basis for the on-site worker is derived from site soil and dust. As mentioned above, it is assumed that the average daily soil/dust ingestion rates for indoor and outdoor workers are 0.02 g and 0.05 g, respectively.

These ingestion rates represent the total amount ingested per 16-hour day in which only 50% of the daily soil/dust ingested originates from site-affected soils. Soils ingested during the 8 hours away from the site are already accounted for in the baseline PbB level (from background sources) that is included in the *AL* model. USEPA omits this adjustment and effectively assumes soils ingested over the entire day are attributable to the site. This adjustment should be made for both indoor and outdoor workers who are exposed to the site soils only 8 hours per day.

Absorption Factor - The absorption factor (AF_s) is the amount of soil lead ingested daily that is absorbed into the circulatory system from the gastrointestinal tract. It is the product of the amount that is in a soluble form in the GI tract and the fraction of soluble lead that is then absorbed into the body. It is a prerequisite that absorbed lead be in a soluble form before it can be absorbed into the body. The AF_s is expressed by the following equation:

$$AF_s = AF_{soluble} * RBF_{soil/soluble}$$

Where:

AF_s	=	Absorption factor for soil.
$AF_{soluble}$	=	Absorption factor for soluble lead.
$RBF_{soil/soluble}$	=	Relative bioavailability in soil compared with soluble lead.

USEPA (1996b) recommends a default value of 0.12 (or 12%) for AF_S, based on the assumption that $AF_{soluble}$ is 0.2 and that $RBF_{soil/soluble}$ is 0.6. These default values represent a weight of evidence determination based on experimental estimates of lead bioavailability in adult humans. They are based on the following factors:

- Dietary status (i.e., lead ingested with a meal *versus* fasting);
- Soil particle size;
- Chemical form of lead (mineralogy); and
- Lead speciation (Steele *et al.* 1990).

The default value of 0.12 for AF_S is likely an upper-bound estimate for women of childbearing age. This value is partly based on the theory that lead absorption increases during pregnancy. Although many physiological changes occur in calcium and lead metabolism, Rothenberg *et al.* (1994) have shown that lead absorption does not increase in pregnant women.

It has been shown that adults absorb only 8% of the soluble lead fraction ($AF_{soluble}$). This average $AF_{soluble}$ value would result in an AF_s value of 0.048 instead of 0.12 (Bowers and Cohen 1996). Therefore, it is recommended that a value of 0.048 should be used in the *AL* model. It may be necessary to discuss this issue with regulatory community prior to running the model.

EXHIBIT 27
UPDATED AL MODEL INPUT PARAMETERS AND CORRESPONDING PRG LEVELS

INPUT PARAMETER	PREVIOUS DEFAULT VALUES	UPDATED VALUES	PARAMETER DESCRIPTION
$PbB_{fetal,\ 0.95,goal}$	10 µg/dL	*NC*	***Target PbB:*** PbB goal of likelihood of a fetal PbB level greater than 10 µg/dL would be less than 5%.
$GSD_{I,adult}$	1.8 or 2.1	1.6	***Geometric Standard Deviation:*** Value of 1.6 is now recommended (White *et al.* 1998; DTSC 1999.)
$R_{fetal/maternal}$	0.9 µg/dL	*NC*	***Ratio Between Fetal and Maternal Blood:*** Based on Goyer (1990) and Graziano *et al.* (1990).
$PbB_{adult,0}$	1.7-2.2 µg/dL	1.4 µg/dL	***Background/Baseline PbB Levels:*** Point estimate should be selected based on site-specific demographics. The value 1.4 is based on NHANES III, Phase 2 (1991-1994).
BKSF	0.4 µg/dL per µg/day	*NC*	***Biokinetic Slope Factor:*** Based on analysis of Pocock *et al.* (1983).
IR_S	0.05 g/day	0.02-0.05 g/day	***Ingestion Rate:*** The value 0.02 represents occupational exposures to indoor soil-derived dust, while 0.05 represents high outdoor direct contact with soil (Stanek and Calabrese 1995.)
EF_S	219 day/yr	*NC*	***Exposure Frequency:*** Based on USEPA (2001) guidance for average time spent at work by both full-time and part-time workers.
AF_S	0.12 (unitless)	0.048	***Absorption Factor:*** Based on an absorption factor for soluble lead of 0.08 and a relative bioavailability of 0.6 soil/soluble (Bowers and Cohen 1996.)
SOIL LEAD PRG CONCENTRATION	**888-1,545 ppm**	**6,473 ppm**	***Preliminary Remediation Goal***

NC – No change

3.11 California LeadSpread Model

3.11.1 Background

California Department of Toxic Substance Control (DTSC) has developed its regulatory lead

model, commonly referred to as the LeadSpread Model. DTSC typically recommends that its model be used at lead sites in California. Because the model is based on default values developed by DTSC and the model has not been validated with actual blood lead levels at any site, it is strongly recommended that the LeadSpread Model never be used as a stand-alone model at any Navy site. At minimum, the LeadSpread Model should always be used with the *IEUBK*, Adult Lead Model, or the *ISE* Model. It would be preferable to run all available models, compare predicted blood lead levels for each model and identify the most scientifically tenable results. Compared with the potential cost of remediation, the cost of running *all* available models is negligible.

Like USEPA lead risk assessment models, the purpose of the California Department of Toxic Substance Control *LeadSpread* model (Ca*LS*) is to predict PbB levels in potentially exposed receptors. The Ca*LS* model has been developed to predict PbB levels in the following receptors:

- Average Child;
- Pica Child (pathological soil ingestion);
- Adults-Residential; and
- Adults-Occupational.

DTSC recently (March 2000) released a beta Version 7 Ca*LS* model that replaces Version 6. Both models share the same computational structure used to estimate PbB levels, but Version 7 has been updated to include more recent default parameters. It is important to evaluate these default values carefully to determine whether they represent site-specific conditions. Unlike the *IEUBK* model, with which USEPA strongly encourages using site-specific input parameters to accurately predict PbB levels, California DTSC's risk assessment/management policy is just the reverse. The DTSC's policy is to preferentially use default values unless compelling evidence and justification is available to permit using alternate values.

The Ca*LS* model relies on a slope factor approach much like the *AL* model, which likely oversimplifies the toxicological aspects of lead. It may not be applicable to all exposure situations, sites, and child populations, and the relationship between lead exposure and PbB levels is not always linear. That is, PbB levels do not always increase in direct proportion to exposure levels (note that for these reasons, USEPA altered its approach, developed the *IEUBK* model, and no longer uses a slope factor approach to evaluate lead risks). The Ca*LS* should be regarded only

as a screening level tool that can be used to identify sites that warrant further investigation.

Both California's lead risk assessment model and its risk management bright lines are more conservative than USEPA's. Whereas USEPA's acceptable risk level corresponds to an exposure where the probability of a childhood or fetal PbB level exceeding 10 μg/dL is less than 5%, California's health-protective level is much more conservative (DTSC 1999):

> *"The Pb concentration of concern in children and adults is ten micrograms (μg) per deciliter (dL) of whole blood. The point of departure for risk management is a 0.01 risk of exceeding this value."*

Simply stated, California's *de minimus* lead risk policy for children and adults is to limit the *predicted* probability of exceeding the PbB level of 10 μg/dL to less than *1%* (instead of 5%). Although this may not appear to be a insignificant difference, this difference translates to an acceptable soil and dust lead concentration in California that is several hundred ppm *lower* than USEPA's acceptable concentration.

3.11.2 Technical Description-Model Overview

Based on the information of numerous studies at lead-contaminated sites, where soil and dust lead concentrations have been measured and compared with PbB levels measured in the exposed population, it appears that the Ca*LS* model yields implausibly high predicted PbB levels. This may be because it lacks a biological component. The Ca*LS* model predicts PbB levels simply based on soil intake rates only for 1- to 2-year-old children, with or without pica.

The Ca*LS* model by default assumes that a child will continuously ingest soil lead at a particular location 24 hours per day, 7 days a week for the 1- to 2-year exposure duration. In other words, a child is assumed to never leave its property and that children 1 to 2 years old spend most of their time outside directly exposed to soil lead. [In fact, children this young spend minimal time outdoors at this age; according to USEPA (1994b), children 1 to 2 years of age only spend approximately 1 to 2 hours per day outdoors.]

The Ca*LS* model can be directly used without modification to estimate PbB levels in adults. Although USEPA has developed the Adult Lead (*AL*) model, the actual receptor is not an adult but a *fetus*. Although the *AL* model can be slightly modified to predict adult PbB levels, the inherent assumption of the model is that a fetus will be exposed.

With the *CaLS* model, the predicted PbB level is an integrated measure of internal dose reflecting total intake from both site-related and background sources. Total lead sample concentration is generally used as the measure of lead in all environmental media and input with the Ca*LS* model. The Ca*LS* model simply adds the incremental increase in PbB levels associated with the following five intake routes:

- Dietary intake;
- Drinking water intake;
- Soil/dust ingestion intake;
- Inhalation intake; and
- Dermal contact intake.

The total blood lead level is the sum of these five intake exposure routes:

$$\textbf{Total PbB Level} = \textbf{Pb Level}_{diet} + \textbf{Pb Level}_{water} + \textbf{Pb Level}_{soil/dust} + \textbf{Pb Level}_{air} + \textbf{Pb Level}_{dermal}$$

The algorithms used to derive PbB intake for each exposure route and the input parameters are briefly described below:

- **DIETARY INTAKE EQUATION**

$$\textbf{Pb Level}_{diet} = \textbf{Dietary Pb Concentration} * \textbf{Intake Rate} * \textbf{Dietary Slope Factor}$$

Where:

$\textbf{Pb Level}_{diet}$	=	PbB level associated with diet.
Dietary Pb Concentration	=	Assumes that 5.5% of the diet consists of home-grown produce (assumed to contain 0.045% of the soil lead concentration), with the other 94.5% supplied by a homogeneous source with a lead content of 1 μg/kg. Sites having no garden should assume 100% from 1 μg/kg source.

Intake Rate = Amount of food ingested per day (kg/day).

Dietary Slope Factor = Increase in PbB level per amount lead ingested [(µg/dL)/(µg/day)].

- **DRINKING WATER INTAKE EQUATION**

$$Pb\ Level_{water} = Water\ Pb\ Concentration * Intake\ Rate * Drinking\ Water\ Slope\ Factor$$

Where:

$Pb\ Level_{water}$ = PbB level associated with drinking water.

Water Pb Concentration = Site-specific, measured value (µg/L).

Intake Rate = Volume of drinking water ingested per day (L).

Drinking Water Slope Factor = Increase in PbB level per amount lead ingested [(µg/dL)/(µg/day)].

- **SOIL AND DUST INGESTION INTAKE EQUATION**

$$Pb\ Level_{soil/dust} = Soil/Dust\ Pb * Intake\ Rate * Soil/Dust\ Slope\ Factor$$

Where:

$Pb\ Level_{soil/dust}$ = PbB level associated with soil/dust ingestion.

Soil/Dust Pb Concentration = Site-specific, measured value (mg/kg).

Soil/Dust Slope Factor = Increase in PbB level per amount lead ingested [(µg/dL)/(µg/day)].

- **INHALATION INTAKE EQUATION**

$$Pb\ Level_{air} = Atmospheric\ Pb * Inhalation\ Slope\ Factor$$

Where:

***Pb Level**$_{air}$*	=	PbB level associated with inhaling air.
Air Pb Concentration	=	Local or regional ambient level (μg/m^3).
Inhalation Slope Factor	=	Increase in PbB level per amount inhaled [(μg/dL)/(μg/m^3)].

- **DERMAL CONTACT INTAKE EQUATION**

***Pb Level**$_{dermal}$ = Soil/Dust Pb Concentration * Contact Rate * Dermal Slope Factor*

Where:

***Pb Level**$_{water}$*	=	PbB level associated with dermal absorption through the skin.
Soil/Dust Pb Concentration	=	Site-specific, measured value (mg/kg).
Contact Rate	=	Amount of soil/dust contact per day (gm/day).
Dermal Slope Factor	=	Increase in PbB level per amount absorbed [(μg/dL)/(μg/day)].

3.11.3 Default Input Parameters

DTSC has developed a set of updated default values for the Ca*LS* model, as shown in Exhibit 28. It is important to note that, while lead concentrations have been dramatically decreasing in all environmental media, the acceptable soil lead concentration represented by the preliminary remediation goal has been lowered rather than increased. This is counterintuitive, since the PbB level is simply the sum of all potential lead exposures from all environmental media. With decreasing lead in air, food, etc., it would seem that the acceptable lead soil concentration would actually increase, not decrease. DTSC provides no explanation to reconcile the apparent paradox created in lowering the acceptable soil lead concentration.

EXHIBIT 28
CALIFORNIA DTSC LEADSPREAD PREVIOUS AND UPDATED RESIDENTIAL DEFAULT INPUT PARAMETERS

INPUT PARAMETER	UNITS	PREVIOUS VALUE (V. 6) [1]	CURRENT VALUE (V.7) [2]	REFERENCE
GENERAL				
Geometric Std. Deviation	Unitless	1.42	1.60	White *et al.* 1998
Background Airborne Lead	µg/m^3	0.18	0.028	CARB 1999
Source-Specific Airborne Dust	µg/m^3	50	1.5	Cowherd et. al 1985
Lead In Drinking Water	µg/L	15	15	MCL
% Diet Home-Grown (Resident)	%	5.5	7	USEPA 1996
% Diet Home-Grown (Worker)	%	0	0	
Daily Food Consumption	kg/day	1.3	1.1	Bolger et. al. 1996
RESIDENTIAL CHILD				
Dietary Lead	µg/kg	10	2.8	USFDA 1996
Soil Ingestion	mg/day	55	100	USEPA 1996
Soil Ingestion, Pica Child	mg/day	790	200	USEPA 1996
Ventilation Rate	m3/day	10	6.8	USEPA 1996
Exposed Skin Area	Cm2	2,800	2,900	USEPA 1996
Soil-To-Skin Adherence	mg/cm2	1	0.2	USEPA 1996
Preliminary Remediation Goal-Soil Lead Concentration (PRG)	Ppm	247	146	DTSC
RESIDENTIAL ADULT				
Daily Food Consumption	kg/day	2.2	1.9	Bolger et. al. 1996
Dietary Lead	µg/kg	10	1.3	USFDA 1996
Soil Ingestion	mg/day	25	50	USEPA 1996
Exposed Skin Area, Resident.	cm^2	3,700	5,800	USEPA 1996
Soil-To-Skin Adherence	mg/cm^2	1	0.07	USEPA 1996
Preliminary Remediation Goal-Soil Lead Concentration	Ppm	1062	676	DTSC

Notes: Table compares default parameters in the previous LeadSpread Version 6 with updated parameters in Version 7.

CARB = California Air Resource Board; USFDA = U.S. Food and Drug Administration; DTSC = California Department of Toxic Substance Control

The relative contributions to the overall PbB level associated with each pathway for the following receptor types are presented in Exhibits 30 and 31:

- Child resident;
- Pica child;
- Adult resident; and
- Occupational worker.

Collecting the correct soil and dust data to predict PbB levels with the Ca*LS* model is a pivotal step in the lead risk assessment. The sampling design should yield an exposure point concentration that represents the average concentration of soil/dust contacted over a relatively long exposure period. Although California Department of Toxic Substance Control guidance recommends using the 95 UCL on the mean soil lead concentration, the average concentration should be used to be consistent with the structure of the model as stated:

> *"The model assumes a log-normal distribution with a GSD of 1.42 and uses this information to estimate the fiftieth, ninetieth, ninety-fifth, ninety-eighth, and ninety-ninth percentile blood Pb concentration for a set of inputs. Since this distribution reflects the physiologic and behavioral variables including soil consumption, using upper bound values for contact rates would distort the percentiles corresponding to blood Pb concentrations."*

Only in circumstances where there is great uncertainty in the dataset should the 95 UCL be used in the Ca*LS* model.

Additionally, the exposure point concentration should represent the average exposure within the exposure unit for the environmental media that will be contacted. For a normal child in the Ca*LS* model, this would primarily be dust lead, not soil lead. Additionally, the default assumption that all sites will have a garden of sufficient size and nutrient quality to provide a significant portion of the diet may be incorrect for most sites. If site-specific conditions preclude an on-site garden, this lead source and exposure route can be excluded from the Ca*LS* model risk assessment. Where eating homegrown produce cannot be eliminate from the risk assessment for future exposures, care should be exercised to use the soil lead concentration in the area where the garden

could reasonably be located. For example, soil samples collected near the drip-line should not be used to estimate PbB levels associated with eating homegrown produce because it is not reasonable to assume a garden will be planted so near the house.

Many of the values used in the Ca*LS* V.7 conflict with default values developed by USEPA, which are currently used in both *IEUBK* and *AL* models, as well as updated peer review studies. Exhibit 29 presents Ca*LS* (V.7) default input parameters with updated values based on more recent studies. Only those values that make a significant difference in the predicted result are presented.

EXHIBIT 29
COMPARING CALS (V.7) VALUES AND UPDATED VALUES FOR SIGNIFICANT INPUT PARAMETERS

INPUT PARAMETER	Ca*LS* MODEL VALUE (V.7)	UPDATED[(1)] VALUES	REFERENCE
GENERAL			
Drinking Water Lead	15	4 ppm	USEPA 1994
GSD	1.6	1.4	NHANES III, Phase 2
Soil Ingestion Rate	50 mg/day	20 mg/day	USEPA 2001
Dust/Soil Ratio	70%	70%	USEPA 1994
Bioavailability	44%	4.8%	Bowers and Cohen 1996
Bioavailability	44%	12%	USEPA 1997
Bioavailability	44%	30%	USEPA 1997

(1) Updated values are based on references presented.

Exhibits 30 and 31 present estimated PRGs results from the Ca*LS* model (V.7) based on default DTSC input parameters for the 95th and 99th percentile individual, as well as the results from a combination of DTSC default parameters and revised parameters that better represent most site conditions. With one exception (Bowers and Cohen reference), all the revised parameters have been developed by USEPA and are recommended as the best estimates for predicting PbB levels and health-protective cleanup goals for both childhood and adult exposures. Replacing only a few input parameters results in significant differences. It is also apparent that the default assumption that all residential sites will have homegrown gardens that will yield sufficient

produce to eat throughout the year has a major impact on the results. Another questionable default parameter is the background drinking water lead concentration. Although *all* input parameters are supposed to represent the average or mean value (because the GSD is subsequently applied to the mean PbB level and used to protect the 95th or 99th percentile individual), the default assumption is that all municipal drinking water sources will be maintained at an *average* corresponding to the Maximum Contaminant Level (MCL; 15 µg/L). However, the MCL represents the *upper limit* of drinking water concentrations that should not be exceeded. The MCL does not represent the average drinking water lead concentration. Furthermore, the latest USEPA survey of municipal drinking water supplies showed the average lead concentration far below the MCL (the mean concentration was approximately 4 ppm), with lead not detected in many samples.

Exhibits 30 and 31 present "*Preliminary* Remediation Goals" derived using the Ca*LS* model with default input values and updated values. A final decision on whether they are health protective or overly-health protective can only be made with site-specific investigations.

EXHIBIT 30
RESIDENTIAL PRELIMINARY REMEDIATION GOALS BASED ON DEFAULT AND UPDATED INPUT PARAMETERS USING CALS MODEL

EXPOSED INDIVIDUAL	INPUT PARAMETER			PRELIMINARY REMEDIATION GOAL			
		Default Input Value	Revised Input Value	DTSC Default PRG		Updated PRG	
				95th Percentile	99th Percentile	95th Percentile	99th Percentile
RESIDENTIAL EXPOSURES							
Child							
DTSC-Child Ingesting Garden Produce				247 ppm	146 ppm		
DTSC-Child Not Ingesting Garden Produce				435 ppm	255 ppm		
Child Ingesting Garden Produce	*Drinking Water Lead*	15 ppm	4 ppm			369 ppm	245 ppm
	Bioavailability	44%	30%				
Child Not Ingesting Garden Produce	*Drinking Water Lead*	15 ppm	4 ppm			783 ppm	519 ppm
	Bioavailability	44%	30%				
Adult							
Adult Ingesting Garden Produce				1,062 ppm	676 ppm		
Adult Not Ingesting Garden Produce				3,793 ppm	2,407 ppm		
Adult Ingesting Garden Produce	*Drinking Water Lead*	15 ppm	4 ppm				
	GSD	1.6	1.4				
	Bioavailability	44%	4.8%			2,111 ppm	1,634 ppm
	Bioavailability	44%	12%			1,991 ppm	1,540 ppm
Adult Not Ingesting Garden Produce	*Drinking Water Lead*	15 ppm	4 ppm				
	GSD	1.6	1.4				
	Soil Ingestion Rate	50	20				
	Bioavailability	44%	4.8%			115,623 ppm	89,374 ppm
	Bioavailability	44%	12%			47,801 ppm	36,949 ppm

EXHIBIT 31
NONRESIDENTIAL PRELIMINARY REMEDIATION GOALS BASED ON DEFAULT AND UPDATED INPUT PARAMETERS USING CALS MODEL

EXPOSED INDIVIDUAL	INPUT PARAMETER	Default Input Value	Revised Input Value	PRELIMINARY REMEDIATION GOAL			
				DTSC Default PRG		Revised PRG	
				95th Percentile	99th Percentile	95th Percentile	99th Percentile
NON-RESIDENTIAL EXPOSURES							
DTSC-Outdoor Worker				5,452 ppm	3,468 ppm		
Outdoor Worker High And Low Bioavailability	***Drinking Water Lead***	15 ppm	4 ppm				
	GSD	1.6	1.4				
	Bioavailability	44%	4.8%			70,719 ppm	54,704 ppm
	Bioavailability	44%	12%			20,696 ppm	15,998 ppm
DTSC-Indoor Worker (1) (Adjusted)				7,087 ppm(1)	4,508 ppm(1)		
Indoor Worker High And Low Bioavailability	***Drinking Water Lead***	15 ppm	4 ppm				
	GSD	1.6	1.4				
	Soil Ingestion Rate	50	20				
	Dust/Soil Ratio	70%	70%				
	Bioavailability	44%	4.8%			132,088 ppm	170,758 ppm
	Bioavailability	44%	12%			54,704 ppm	70,719 ppm

(1) The default indoor worker PRG for soil was derived from the outdoor worker PRG soil by applying the default relationship between soil and dust described by C*dust* = 0.7 * C*soil.* That is, since it is presumed that indoor dust is only 70% of the outside soil concentration and indoor workers contact dust lead, rather than soil lead, the PRG for soil lead should be based on its contribution to indoor dust lead.

3.12 Integrated Stochastic Exposure Model

3.12.1 Background

The *Integrated Stochastic Exposure* (*ISE*) model is a probabilistic model that is considered a

next-generation risk assessment tool for predicting PbB level. The advantages of the *ISE* model are numerous; however, the principle advantage is that it yields more accurate PbB level predictions. That is, the *ISE*-predicted PbB levels more accurately match measured PbB levels in exposed populations. For this reason alone, it should be used in conjunction with—or as a replacement for—the *IEUBK* model in making accurate and precise lead risk estimates at all Navy Installations.

3.12.2 Technical Description—Model Overview

The *ISE* is a probabilistic lead model. As noted in numerous sections of this report, lead models previously discussed are deterministic and often over predict actual site-specific PbB levels, which can lead to unnecessary and costly remediation, as revealed in recent biomonitoring studies. Although the *IEUBK* model is fundamentally correct, it appears the deterministic manner of the calculations introduces unacceptable conservatism into the calculations. This is termed compounding conservatism. Although each single value may appear to represent the "best" available value, the combination of many conservative (sometimes referred to as "health protective") values for each parameter for each environmental medium results in implausible results that are not empirically observed.

In contrast, the *ISE* model circumvents the limitations of a deterministic approach by implementing a probabilistic method. Detailed guidance for conducting probabilistic risk assessments is presented in "*Risk Assessment Guidance For Superfund: Volume 3 -Part A, Process For Conducting Probabilistic Risk Assessment"* (USEPA 1999b).

Probabilistic risk assessments model exposure and risks to a population of human receptors by iteratively calculating risk for each person in an exposed population. The procedure involves iteratively solving the same equation (representing risk) using a randomly chosen set of parameters to represent an individual's exposure. Thus, the risk result from each iteration represents a single individual. Each subsequent iteration adds another person to the population, and combining the results presents a statistical model of the entire exposed population. Iterations are typically conducted 5,000 to 10,000 times to represent a relatively large exposed population. This process allows any individual risk, such as the 95^{th} percentile individual, to be easily identified and quantified within the population.

Until recently, probabilistic risk assessments were only recommended for chemicals other than lead. However, recent work by EPA Region 8 in developing the *ISE* model has now provided

preliminary evidence that a probabilistic approach is not only appropriate for lead risk assessments, but can yield a more precise risk estimate compared with the *IEUBK*, *AL*, and *CaLS* lead risk assessment models, which are all deterministic models.

EPA Region 8 (Griffin *et al.* 1999) recently conducted a detailed investigation to determine the predictive power of the *ISE* model and to compare the performance of the model under actual exposure conditions at another Superfund site with the *IEUBK* model. Exhibit 32 shows that the *ISE* model closely predicted actual measured PbB levels very closely, while the *IEUBK* model over-estimated PbB levels. If the *ISE* and Agency for Toxic Substances and Disease Registry (ATSDR) results had not been available, and risk management decisions were made based solely on the *IEUBK* results, it is likely that very costly and unnecessary remediation and intervention measures would have been implemented. Furthermore, because the *IEUBK* -estimated PbB levels represent the mean PbB levels, the overestimated PbB levels could have precipitated emergency medical treatment, including chelation therapy for children. Instead, based on the results of the ATSDR study, no further action is required.

EXHIBIT 32

COMPARING ISE AND IEUBK MODEL PREDICTED PBB LEVELS WITH ACTUAL MEASURED PBB LEVELS FOR MURRAY SITE RESIDENTS

RISK ASSESSMENT METHOD	MEAN PBB LEVEL (μG/DL)
ATSDR – Actual Measured PbB Levels (n=9)	4.8 μg/dL
***ISE* – Predicted PbB Levels**	5.3 μg/dL
***IEUBK* – Predicted PbB Levels**	17.5 μg/dL

3.12.3 Input Parameters

Input parameters for the *ISE* model are presented in Exhibit 33. As shown, the default parameters are the distributions of possible values, rather than "best estimates."

EXHIBIT 33
INPUT VALUES FOR THE ISE MODEL BY EXPOSURE PATHWAY

EXPOSURE PATHWAY	EXPOSURE VARIABLE		PROBABILITY DISTRIBUTIONS FOR EXPOSURE VARIABILITY		
	SYMBOL	DESCRIPTION	PDF	PARAMETERS	SOURCE
Soil/Dust Ingestion	C_{soil}	Soil Pb concentration (ppm)	Lognormal	Arithmetic mean, Standard deviation	ISZ site data
	C_{dust}, Regression A	Dust Pb concentration (ppm)	Point Estimate	174	ISZ site data
	C_{dust}, Regression B	Soil ingestion rate (mg/kg)	Point Estimate	0.19	ISZ site data
	$IR_{soil/dust}$	Weighting factor, age (unitless)	Empirical Continuous	(0,10,45,88,186,208,225,7000) (0,0.25,0.5,075,0.9,.095,0.99,1.0)	Stanek and Calabrese 1995
	WF_{age}	Weighting factor, soil (unitless)	Point Estimate	*IEUBK*	USEPA 1994b
	WF_{soil}	Weighting factor, soil (unitless)	Triangular	(min, mode, max) = (0.3, 0.45, 0.6)	Mode: USEPA 1994b min, max Pope 1985
	$AF_{soil/dust}$	Absorption fraction (%)	Triangular	(min, mode, max) = (23, 36,48)	USEPA 1996c
Dietary Intake	$Intake_{diet}$	Intake rate (μgPb/day)	Point Estimate	70% * *IEUBK* default	Gunderson *et al.* 1995
Water Ingestion	All exposure variables		Point Estimate	*IEUBK*	USEPA 1994b
Air Inhalation	All exposure variables		Point Estimate	*IEUBK*	USEPA 1994b
All	EF	Exposure Frequency (days/year)	Triangular	(min, mode, max) = (200, 234, 350)	USEPA 1993

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